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7 Attorneys for Defendant  
8 VARIAN MEDICAL SYSTEMS, INC.

9 UNITED STATES DISTRICT COURT  
10 NORTHERN DISTRICT OF CALIFORNIA  
11 SAN FRANCISCO DIVISION

12 UNIVERSITY OF PITTSBURGH OF THE  
13 COMMONWEALTH SYSTEM OF HIGHER  
14 EDUCATION d/b/a UNIVERSITY OF  
15 PITTSBURGH, a Pennsylvania non-profit  
corporation (educational),

16 Plaintiff,

17 v.

18 VARIAN MEDICAL SYSTEMS, INC., a  
Delaware corporation,

19 Defendant.

Case No. CV 08-02973 MMC

**DECLARATION OF MATTHEW H.  
POPPE IN SUPPORT OF VARIAN'S  
ADMINISTRATIVE MOTION TO FILE  
UNDER SEAL EXHIBITS TO SEALED  
POPPE DECLARATION**

1 I, Matthew H. Poppe, declare as follows:

2 1. I am an attorney licensed to practice in the State of California. I am a partner in  
3 the law firm of Orrick, Herrington & Sutcliffe LLP ("Orrick"), counsel of record for Defendant  
4 Varian Medical Systems, Inc. ("Varian") in this action. Except as indicated herein, I have  
5 personal knowledge of the facts and circumstances of the matters set forth in this Declaration. If  
6 called as a witness, I could and would testify competently to the matters set forth herein.

7 2. I make this declaration in support of Varian's Administrative Motion to File Under  
8 Seal Exhibits to Sealed Poppe Declaration.

9 3. In an action between the parties in the United States District Court for the Western  
10 District of California, Case No. 2:07-CV-00491-AJS (the "Related Case"), Plaintiff University of  
11 Pittsburgh ("UPitt") filed a Complaint alleging patent infringement against Varian. A true and  
12 correct copy of this document is attached as Exhibit A.

13 4. The Court in the Related Case entered a Protective Order on May 24, 2007, which  
14 prohibits Varian from filing in the public record any discovery material that has been designated  
15 as "Confidential" or "Confidential – Attorney Eyes Only" by any party or non-party in that case.  
16 A true and correct copy of this document is attached as Exhibit B.

17 5. Each of the exhibits to the Sealed Declaration of Matthew H. Poppe in Support of  
18 Varian's Motion to Transfer Action to U.S. District Court for Western District of Pennsylvania  
19 has been designated "Confidential" or "Confidential – Attorney Eyes Only" by either UPitt or a  
20 non-party pursuant to the terms of the Stipulated Protective Order governing the Related Case.

21 I declare under penalty of perjury under the laws of the United States that the foregoing is  
22 true and correct.

23 Executed this 27th day of June, 2008 at Menlo Park, California.

24  
25 /s/ Matthew H. Poppe

26 Matthew H. Poppe

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of DECLARATION OF MATTHEW H. POPPE IN SUPPORT OF VARIAN'S ADMINISTRATIVE MOTION TO FILE UNDER SEAL EXHIBITS TO SEALED POPPE DECLARATION was served upon the University of Pittsburgh, through its counsel, via:

_____	Hand-Delivery
_____	Facsimile
_____	First Class, US Mail, Postage Prepaid
_____	Certified Mail-Return Receipt Requested
<u>  X  </u>	ECF Electronic Service
_____	Overnight Delivery

at the following addresses:

Rita E. Tautkus  
Morgan Lewis & Bockius, LLP  
One Market – Spear Street Tower  
San Francisco, CA 94105  
[rtautkus@morganlewis.com](mailto:rtautkus@morganlewis.com)

Dated: July 2, 2008

/s/ Matthew H. Poppe  
Matthew H. Poppe

# **EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

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UNIVERSITY OF PITTSBURGH,

Plaintiff,

v.

VARIAN MEDICAL SYSTEMS, INC.,

Defendant.

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CIVIL ACTION

No.

**JURY TRIAL DEMANDED**

**COMPLAINT**

**The Parties**

1. Plaintiff University of Pittsburgh ("Plaintiff") is an academic institution with its principle place of business in Pittsburgh, Pennsylvania.
2. Upon information and belief, defendant Varian Medical Systems, Inc. ("Varian") is a Delaware corporation with its principle place of business in Palo Alto, California.

**Jurisdiction and Venue**

3. This action arises under the patent laws of the United States. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.
4. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b).

**Count I  
(Claim for Patent Infringement)**

5. Plaintiff is the owner of the entire right, title and interest in and to United States Patent No. 5,727,554 ("the '554 patent"), and United States Patent No. 5,784,431 ("the '431 patent"), referred to collectively herein as the "Patents-In-Suit" each of which pertains to the

Plaintiff's image-guided radiation therapy technology. A true and correct copy of each of the Patents-In-Suit is attached hereto as Exhibits A and B.

6. Plaintiff alleges on information and belief, that Varian has infringed and continues to infringe the Patents-In-Suit by making, using, offering for sale and/or selling in the United States devices that embody or otherwise practice one or more of the claims of the Patents-In-Suit, or by otherwise contributing to infringement or inducing others to infringe the Patents-In-Suit. These acts constitute violations of 35 U.S.C. § 271.

7. Plaintiff has given notice to Varian that Varian's products and systems embody or otherwise practice the claimed subject matter of the Patents-In-Suit. Varian's infringement of the Patents-In-Suit is, has been, and continues to be willful and deliberate.

8. Unless enjoined by this Court, Varian will continue their acts of infringement causing substantial and irreparable harm to Plaintiff.

9. As a direct and proximate result of Varian's infringement of the Patents-In-Suit, Plaintiff has been and continues to be damaged in an amount yet to be determined.

10. This is an exceptional case within the meaning of 35 U.S.C. § 285, and Plaintiff is accordingly entitled to an award of its attorneys' fees.

### **Request for Relief**

WHEREFORE, Plaintiff demands judgment against Varian as follows:

A. Preliminarily and permanently enjoining and restraining the Varian, its officers, directors, employees, agents, servants, successors and assigns, and any and all persons acting in privity or in concert with Varian, from further infringement of the Patents-In-Suit;

B. Assessing against Varian and awarding to Plaintiff damages sufficient to compensate for Varian's infringement of the Patents-In-Suit, and conducting an accounting to

determine said damages, as provided by 35 U.S.C. § 284;

- C. Increasing said damages to three times the amount found or assessed;
- D. Awarding Plaintiff its costs and disbursements in this action, including reasonable attorneys' fees, as provided by 35 U.S.C. § 285; and
- E. Granting to Plaintiff such other and further relief as this Court may deem just and proper.

**Jury Demand**

Plaintiff hereby demands a jury trial as provided by Rule 38(a) of the Federal Rules of Civil Procedure.

DATED: April 13, 2007

/s/ Christopher K. Ramsey

David W. Marston Jr. (Pa ID No. 84399)

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[allison.young@morganlewis.com](mailto:allison.young@morganlewis.com)

Attorneys for Plaintiff University of Pittsburgh

JS 44 (Rev. 11-04)

## CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

<b>I. (a) PLAINTIFFS</b> UNIVERSITY OF PITTSBURGH  <b>(b)</b> County of Residence of First Listed Plaintiff Pittsburgh  (EXCEPT IN U.S. PLAINTIFF CASES) <b>Christopher K. Ramsey, Morgan Lewis &amp; Bockius, One Oxford Centre, Pgh., PA 15219</b> <b>(c) Attorneys</b> David W. Marston Jr., Morgan, Lewis & Bockius LLP, 1701 Market St  Philadelphia, PA 19103, (215) 963-5937;  (Firm Name, Address, and Telephone Number)	<b>DEFENDANTS</b> VARIAN MEDICAL SYSTEMS, INC.  County of Residence of First Listed Defendant _____  (IN U.S. PLAINTIFF CASES ONLY) NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED  Attorneys _____  Attorneys (If Known) _____
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<b>II. BASIS OF JURISDICTION</b> (Place an "X" in One Box Only)  <input type="checkbox"/> 1 U.S. Government Plaintiff <input checked="" type="checkbox"/> 3 Federal Question (U.S. Government Not a Party)  <input type="checkbox"/> 2 U.S. Government Defendant <input type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III)	<b>III. CITIZENSHIP OF PRINCIPAL PARTIES</b> (Place an "X" in One Box for Plaintiff and One Box for Defendant) (For Diversity Cases Only) <table style="width: 100%;"> <tr> <td style="width: 33%;">Citizen of This State</td> <td style="width: 33%;">PTF <input checked="" type="checkbox"/> 1 DEF <input type="checkbox"/> 1</td> <td style="width: 33%;">Incorporated or Principal Place of Business in This State</td> <td style="width: 33%;">PTF <input type="checkbox"/> 4 DEF <input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td>PTF <input type="checkbox"/> 2 DEF <input checked="" type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business in Another State</td> <td>PTF <input type="checkbox"/> 5 DEF <input checked="" type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td>PTF <input type="checkbox"/> 3 DEF <input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td>PTF <input type="checkbox"/> 6 DEF <input type="checkbox"/> 6</td> </tr> </table>	Citizen of This State	PTF <input checked="" type="checkbox"/> 1 DEF <input type="checkbox"/> 1	Incorporated or Principal Place of Business in This State	PTF <input type="checkbox"/> 4 DEF <input type="checkbox"/> 4	Citizen of Another State	PTF <input type="checkbox"/> 2 DEF <input checked="" type="checkbox"/> 2	Incorporated and Principal Place of Business in Another State	PTF <input type="checkbox"/> 5 DEF <input checked="" type="checkbox"/> 5	Citizen or Subject of a Foreign Country	PTF <input type="checkbox"/> 3 DEF <input type="checkbox"/> 3	Foreign Nation	PTF <input type="checkbox"/> 6 DEF <input type="checkbox"/> 6
Citizen of This State	PTF <input checked="" type="checkbox"/> 1 DEF <input type="checkbox"/> 1	Incorporated or Principal Place of Business in This State	PTF <input type="checkbox"/> 4 DEF <input type="checkbox"/> 4										
Citizen of Another State	PTF <input type="checkbox"/> 2 DEF <input checked="" type="checkbox"/> 2	Incorporated and Principal Place of Business in Another State	PTF <input type="checkbox"/> 5 DEF <input checked="" type="checkbox"/> 5										
Citizen or Subject of a Foreign Country	PTF <input type="checkbox"/> 3 DEF <input type="checkbox"/> 3	Foreign Nation	PTF <input type="checkbox"/> 6 DEF <input type="checkbox"/> 6										

<b>IV. NATURE OF SUIT</b> (Place an "X" in One Box Only)				
<b>CONTRACT</b> <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<b>PERSONAL INJURY</b> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	<b>PERSONAL INJURY</b> <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability  <b>PERSONAL PROPERTY</b> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<b>FORFEITURE/PENALTY</b> <input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other  <b>LABOR</b> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	<b>BANKRUPTCY</b> <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157  <b>PROPERTY RIGHTS</b> <input type="checkbox"/> 820 Copyrights <input checked="" type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark  <b>SOCIAL SECURITY</b> <input type="checkbox"/> 861 HHA (1395(b)) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIW C/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))  <b>FEDERAL TAX SUITS</b> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS-Third Party 26 USC 7609
<b>REAL PROPERTY</b> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<b>CIVIL RIGHTS</b> <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 444 Welfare <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 440 Other Civil Rights	<b>PRISONER PETITIONS</b> <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> Habeas Corpus: <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition	<b>OTHER STATUTES</b> <input type="checkbox"/> 460 State Reapportionment <input type="checkbox"/> 410 Annuities <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeers Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat. TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes	

<b>V. ORIGIN</b> (Place an "X" in One Box Only)						
<input checked="" type="checkbox"/> 1 Original Proceeding	<input type="checkbox"/> 2 Removed from State Court	<input type="checkbox"/> 3 Remanded from Appellate Court	<input type="checkbox"/> 4 Reinstated or Reopened	<input type="checkbox"/> 5 Transferred from another district (specify) _____	<input type="checkbox"/> 6 Multidistrict Litigation	<input type="checkbox"/> 7 Appeal to District Judge from Magistrate Judgment

<b>VI. CAUSE OF ACTION</b>	Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): 35 U.S.C. § 271 Brief description of cause: Patent infringement action
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<b>VII. REQUESTED IN COMPLAINT:</b>	<input type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND \$ _____	CHECK YES only if demanded in complaint: <b>JURY DEMAND:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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<b>VIII. RELATED CASE(S) IF ANY</b>	(See instructions):	JUDGE _____	DOCKET NUMBER _____
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DATE April 13, 2007	SIGNATURE OF ATTORNEY OF RECORD /s/ Christopher K. Ramsey
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FOR OFFICE USE ONLY

RECEIPT # _____	AMOUNT _____	APPLYING IFP _____	JUDGE _____	MAG. JUDGE _____
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JS 44AREVISED OCTOBER, 1993

IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF PENNSYLVANIA

THIS CASE DESIGNATION SHEET MUST BE COMPLETED

## PART A

This case belongs on the ☐ Erie ☐ Johnstown ☒ Pittsburgh) calendar.

1. **ERIE CALENDAR** - If cause of action arose in the counties of Crawford, Elk, Erie, Forest, McKean, Venang or Warren, OR any plaintiff or defendant resides in one of said counties.
2. **JOHNSTOWN CALENDAR** - If cause of action arose in the counties of Bedford, Blair, Cambria, Clearfield or Somerset OR any plaintiff or defendant resides in one of said counties.
3. Complete if on ERIE CALENDAR: I certify that the cause of action arose in \_\_\_\_\_ County and that the \_\_\_\_\_ resides in \_\_\_\_\_ County.
4. Complete if on JOHNSTOWN CALENDAR: I certify that the cause of action arose in \_\_\_\_\_ County and that the \_\_\_\_\_ resides in \_\_\_\_\_ County.

## PART B (You are to check ONE of the following)

1. ☐ This case is related to Number \_\_\_\_\_ Judge \_\_\_\_\_
2. ☒ This case is not related to a pending or terminated case.

## DEFINITIONS OF RELATED CASES:

**CIVIL:** Civil cases are deemed related when a case filed relates to property included in another suit or involves the same issues of fact or it grows out of the same transactions as another suit or involves the validity or infringement of a patent involved in another suit

**EMINENT DOMAIN:** Cases in contiguous closely located groups and in common ownership groups which will lend themselves to consolidation for trial shall be deemed related.

**HABEAS CORPUS & CIVIL RIGHTS:** All habeas corpus petitions filed by the same individual shall be deemed related. All pro se Civil Rights actions by the same individual shall be deemed related.

## PART C

1. CIVIL CATEGORY (Place x in only applicable category).

1. ☐ Antitrust and Securities Act Cases
2. ☐ Labor-Management Relations
3. ☐ Habeas Corpus
4. ☐ Civil Rights
5. ☒ Patent, Copyright, and Trademark
6. ☐ Eminent Domain
7. ☐ All other federal question cases
8. ☐ All personal and property damage tort cases, including maritime, FELA, Jones Act, Motor vehicle, products liability, assault, defamation, malicious prosecution, and false arrest
9. ☐ Insurance indemnity, contract and other diversity cases.
10. ☐ Government Collection Cases (shall include HEW Student Loans (Education), VA Overpayment, Overpayment of Social Security, Enlistment Overpayment (Army, Navy, etc.), HUD Loans, GAO Loans (Misc. Types), Mortgage Foreclosures, S.B.A. Loans, Civil Penalties and Coal Mine Penalty and Reclamation Fees.)

I certify that to the best of my knowledge the entries on this Case Designation Sheet are true and correct

DATE April 13, 2007 ATTORNEY ATTORNEY AT LAW \_\_\_\_\_

NOTE: ALL SECTIONS OF BOTH SIDES MUST BE COMPLETED BEFORE CASE CAN BE PROCESSED.

JS 44 Reverse (Rev. 11/04)

## INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

## Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) **Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) **County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) **Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. **Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below. United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. **Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. **Nature of Suit.** Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. **Origin.** Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts. Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date. Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. **Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553  
Brief Description: Unauthorized reception of cable service

VII. **Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. **Related Cases.** This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

**Date and Attorney Signature.** Date and sign the civil cover sheet.

UNITED STATES  
DISTRICT COURT  
WESTERN DISTRICT OF PENNSYLVANIA  
PITTSBURGH Division

# 07003692 - EA  
April 13, 2007

Code	Case #	Qty	Amount
CIVIL FI 07-491		1 @	350.00
			350.00 CC

TOTAL → 350.00

FROM: MORGAN LEWIS & BOCKIUS  
ONE OXFORD CENTRE  
32ND FLOOR  
PITTSBURGH PA 15222

**EXHIBIT A**

US005727554A

**United States Patent** [19][11] **Patent Number:** 5,727,554

Kalend et al.

[45] **Date of Patent:** Mar. 17, 1998[54] **APPARATUS RESPONSIVE TO MOVEMENT OF A PATIENT DURING TREATMENT/DIAGNOSIS**[75] **Inventors:** Andre M. Kalend, Monroeville; Joel Greenberger, Sewickley; Karun B. Shinoga, Pittsburgh; Charalambos N. Athanassiou, Pittsburgh; Takeo Kanade, Pittsburgh, all of Pa.[73] **Assignee:** University of Pittsburgh of the Commonwealth System of Higher Education, Pittsburgh, Pa.[21] **Appl. No.:** 715,834[22] **Filed:** Sep. 19, 1996[51] **Int. Cl.<sup>6</sup>** ..... A61B 6/00[52] **U.S. Cl.** ..... 128/653.1[58] **Field of Search** ..... 128/630, 653.1,  
128/660.03; 364/413.02, 413.13, 413.25,  
413.26; 356/375; 378/69, 205[56] **References Cited****U.S. PATENT DOCUMENTS**

4,466,075	8/1984	Groch et al.	364/413.26	X
5,080,100	1/1992	Trotel	128/653.1	
5,103,823	4/1992	Acharya et al.	128/653.1	
5,214,711	5/1993	Neely et al.	364/413.27	X
5,295,483	3/1994	Nowacki et al.	128/660.03	
5,389,101	2/1995	Heilbrun et al.	128/653.1	X
5,398,684	3/1995	Hardy	128/653.1	
5,446,548	8/1995	Genig et al.	128/653.1	X
5,482,042	1/1996	Fujita	128/653.1	
5,558,430	9/1996	Bova et al.	128/653.1	

**OTHER PUBLICATIONS**

Active Shape Models—"Smart Snakes", T.F. Cootes and C.J. Taylor, pp. 267-275, Proceedings of European Conference on Computer Vision, Genoa, Italy, 1992.

Training Models of Shape from Sets of Examples, T.F. Cootes, C.J. Taylor, D.H. Cooper, and J. Graham, pp. 8-18, Proceedings of European Conference on Computer Vision, Genoa, Italy, 1992.

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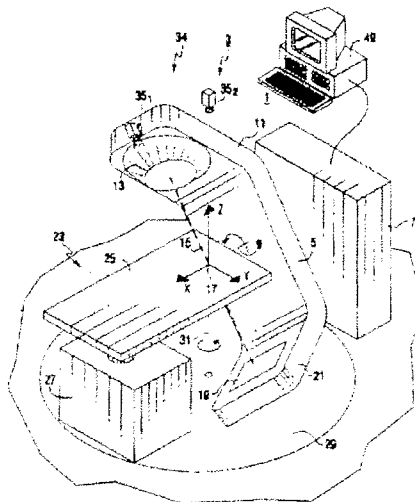
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*Primary Examiner*—Francis Jaworski

*Attorney, Agent, or Firm*—Richard V. Westerhoff; Eckert Seamans Cherin & Mellott, LLC

[57] **ABSTRACT**

A camera generates digital image signals representing an image of one or more natural or artificial fiducials on a patient positioned on treatment or diagnosis equipment. A processor applies multiple levels of filtering at multiple levels of resolution to repetitively determine successive fiducial positions. A warning signal is generated if movement exceeds certain limits but is still acceptable for treatment. Unacceptable displacement results in termination of the treatment beam. Tracking templates can be generated interactively from a display of the digital image signals or through automatic selection of an image having the median correlation to an initial template. A gating signal synchronized to patient breathing can be extracted from the digital image signals for controlling the radiation beam generator.

**22 Claims, 12 Drawing Sheets**

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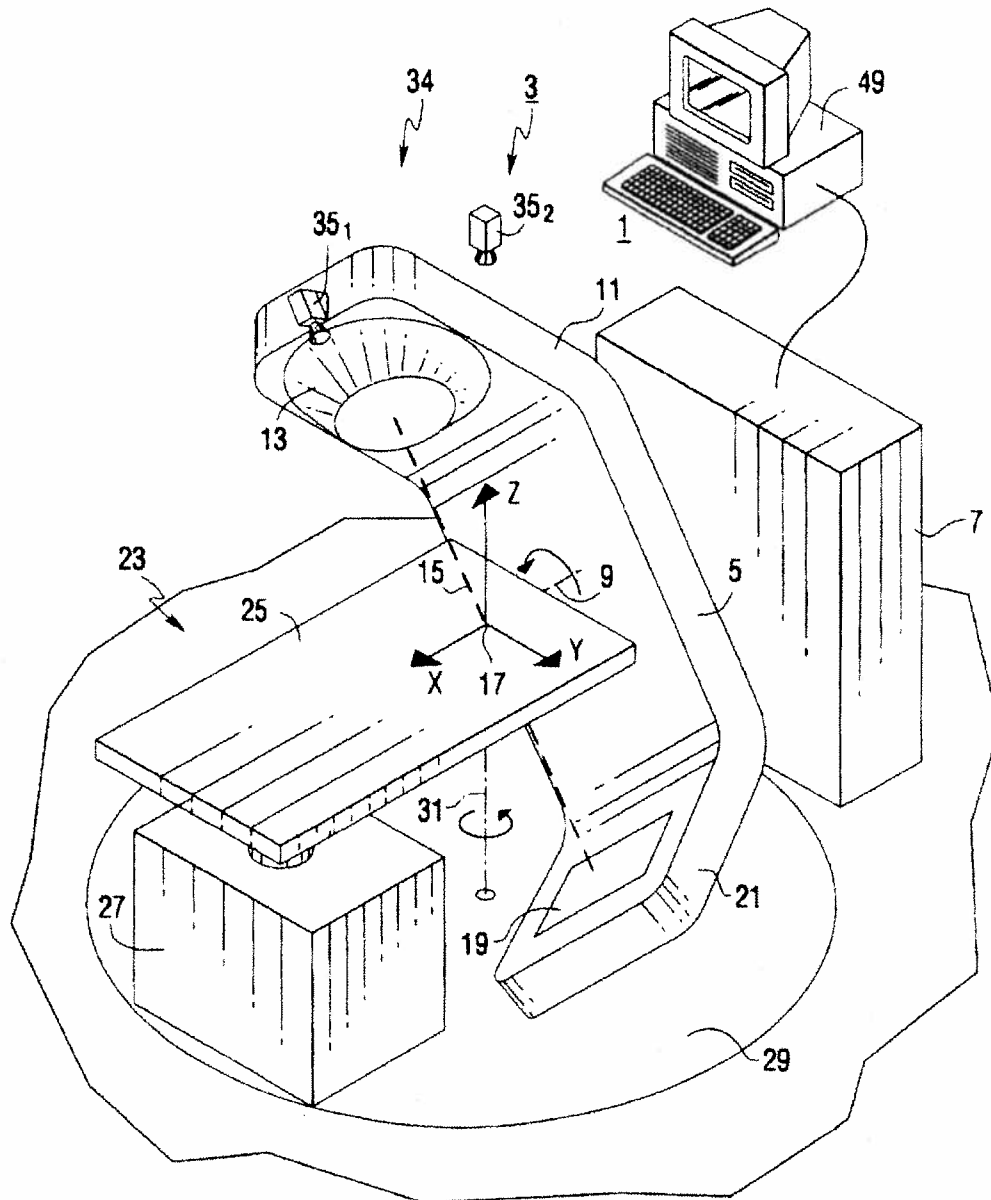


FIG. 1

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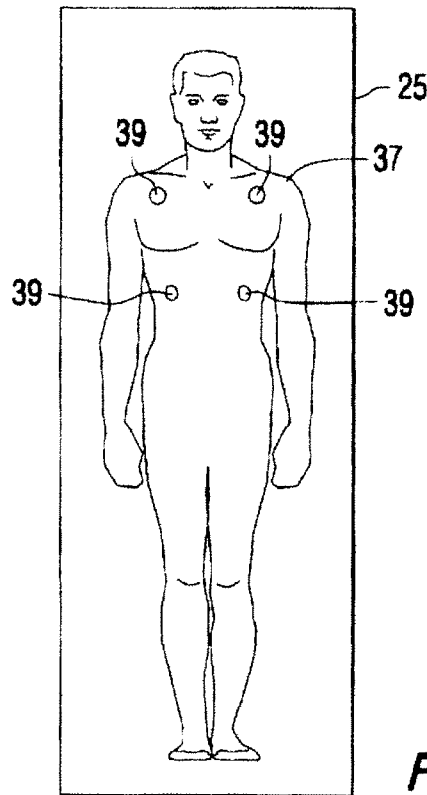


FIG. 2

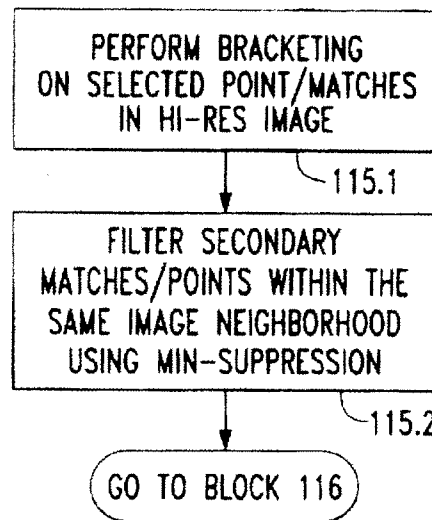


FIG. 9

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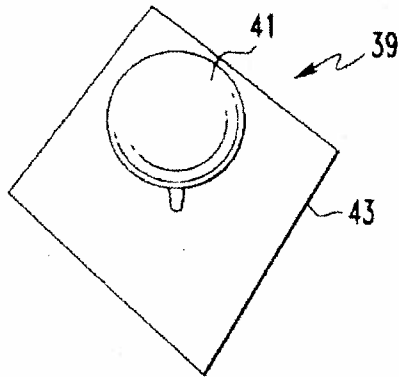


FIG. 3

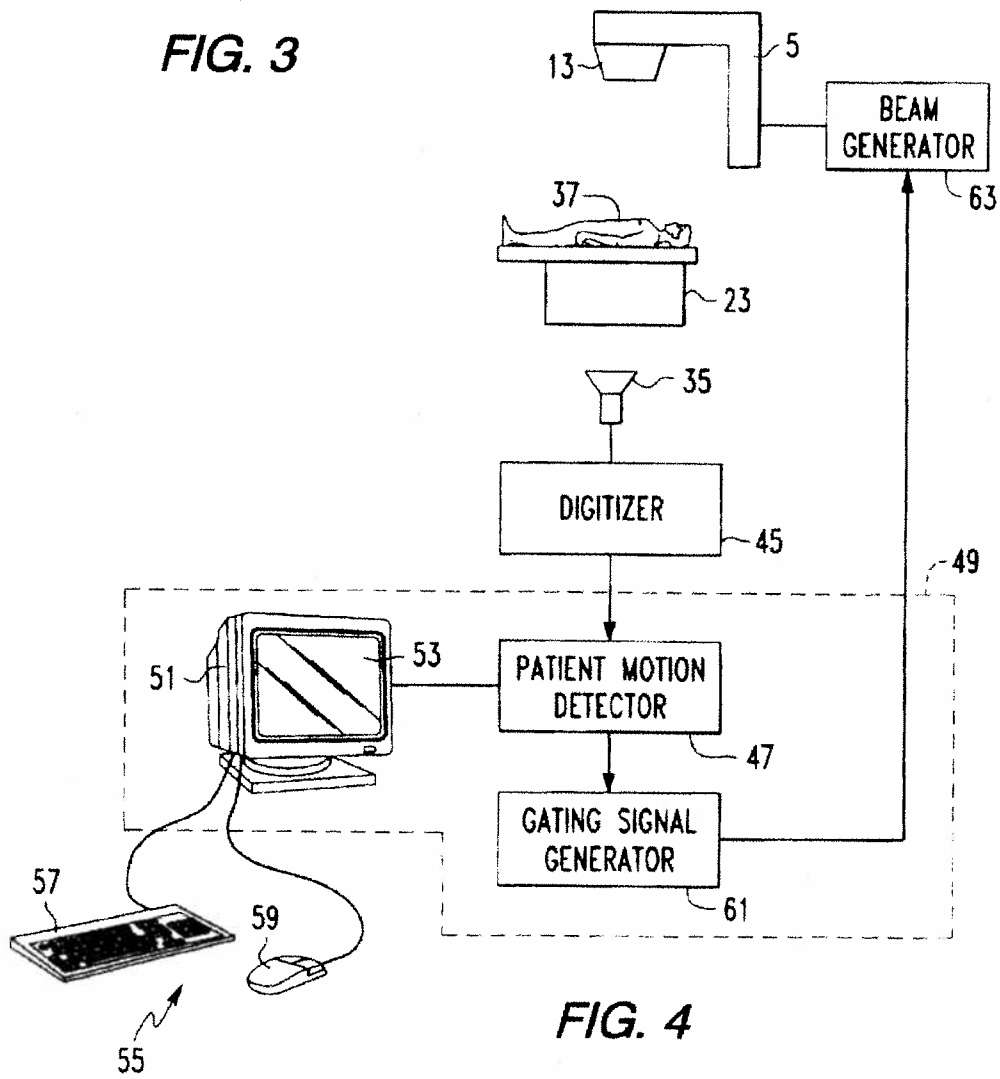


FIG. 4



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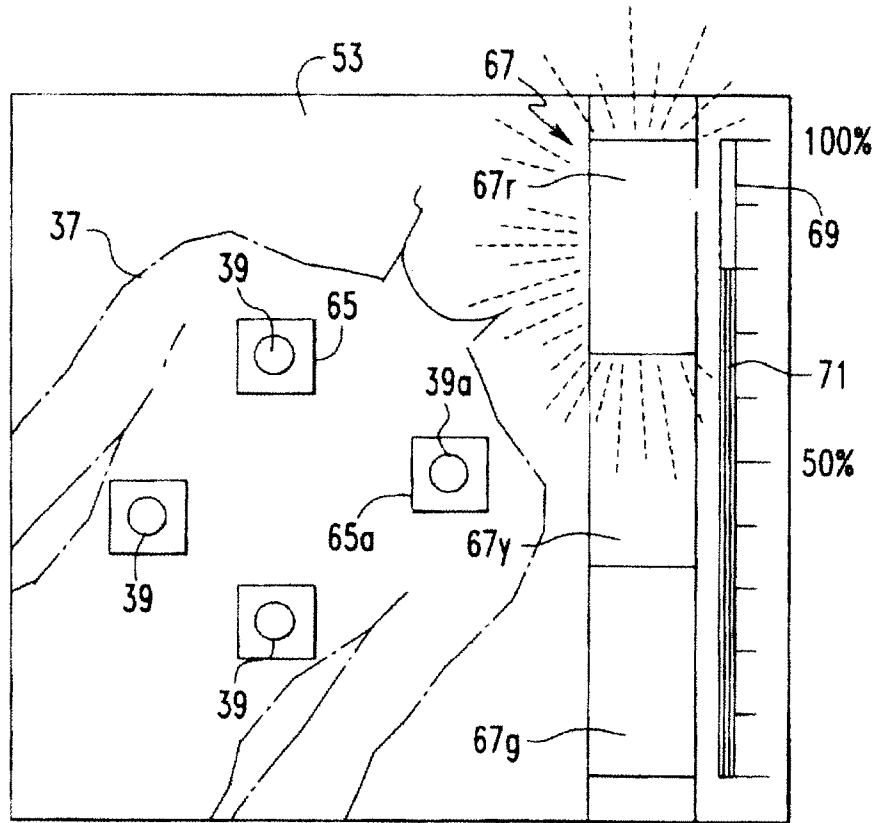


FIG. 5

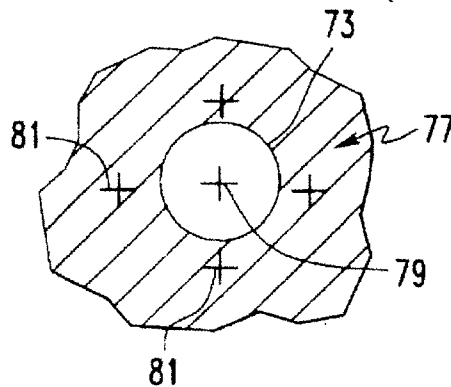


FIG. 17

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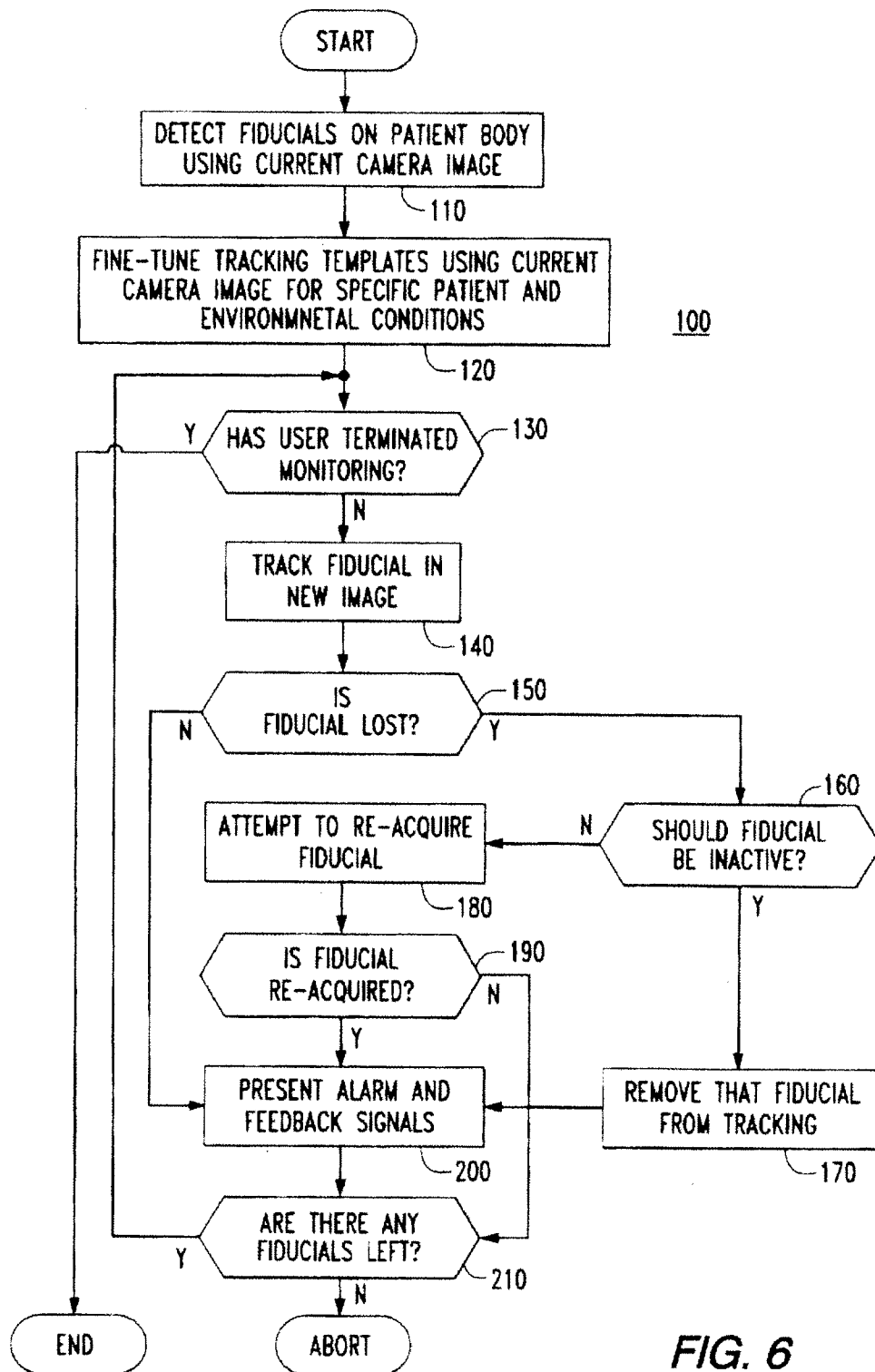


FIG. 6

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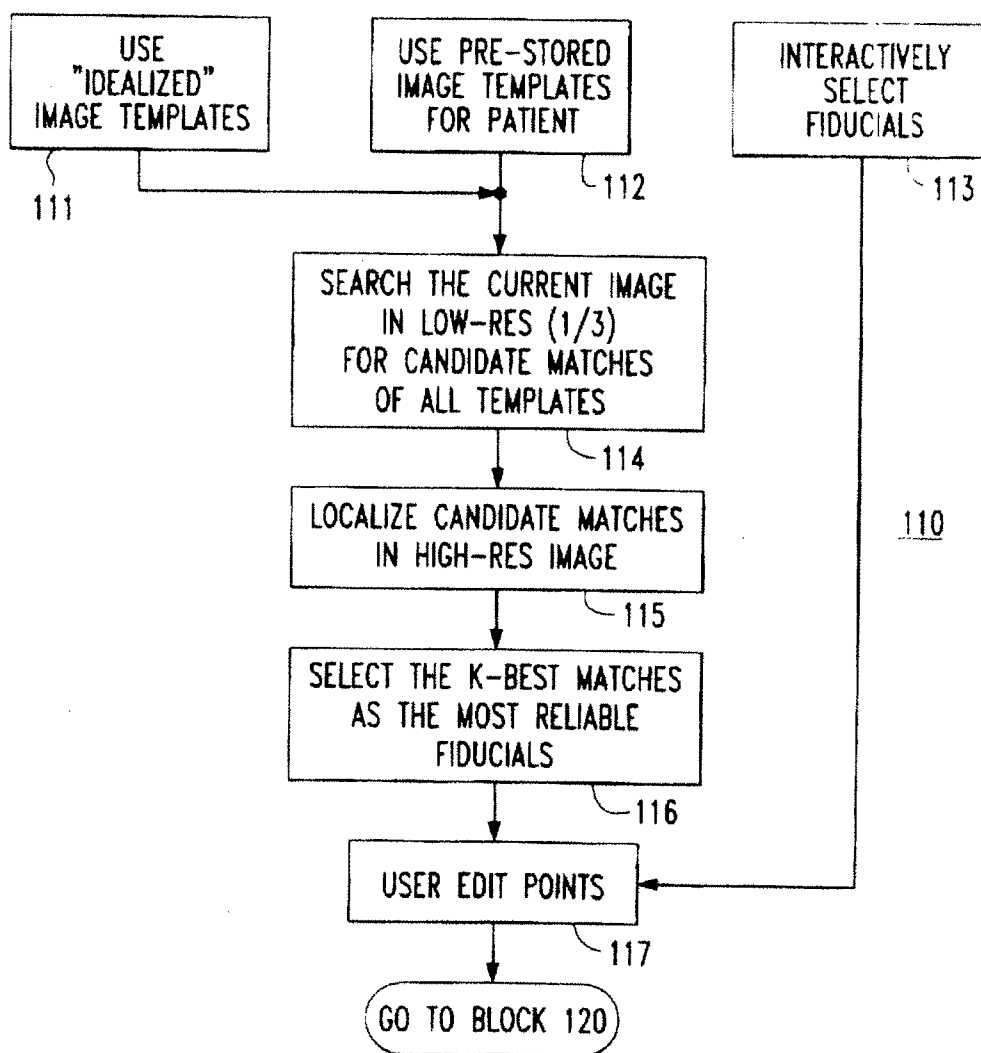


FIG. 7

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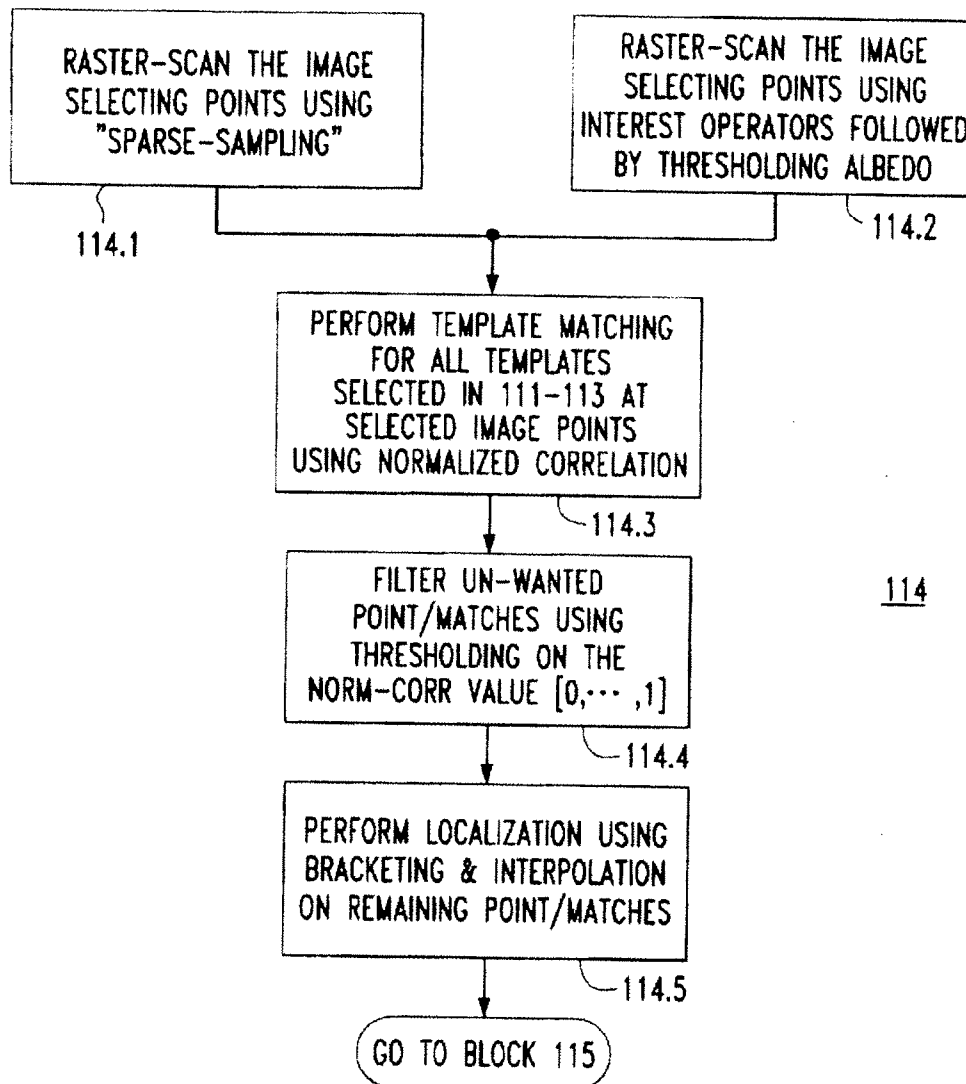


FIG. 8

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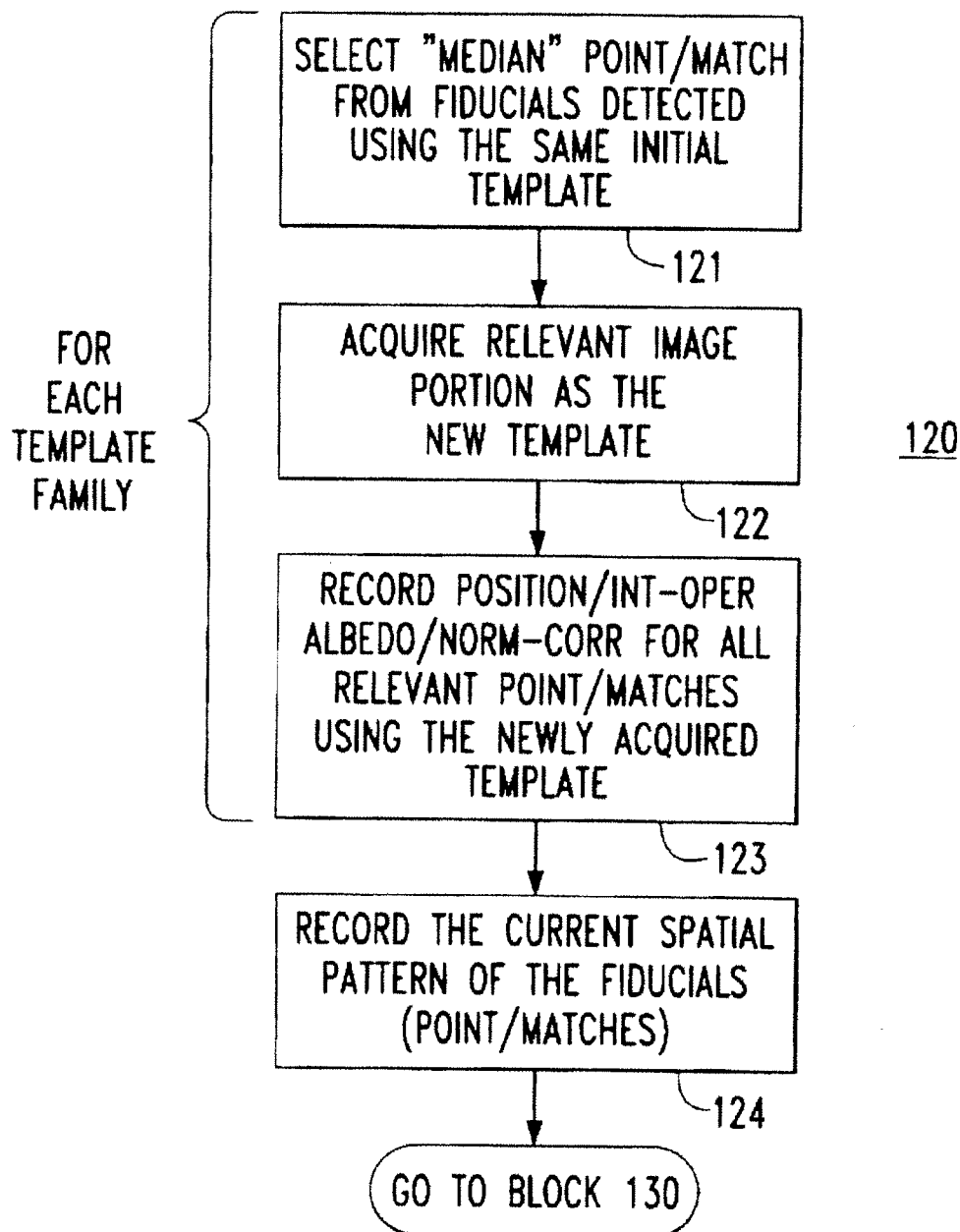


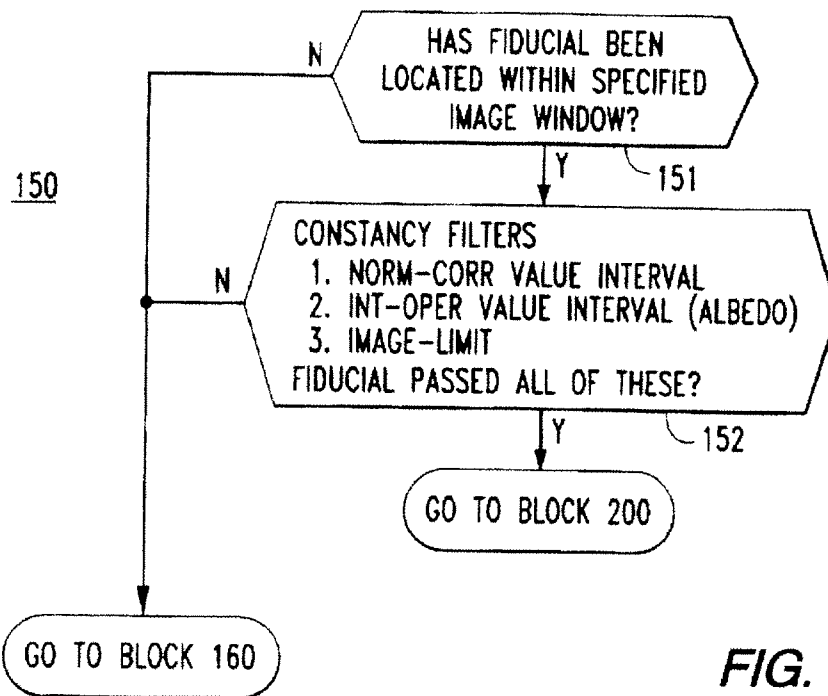
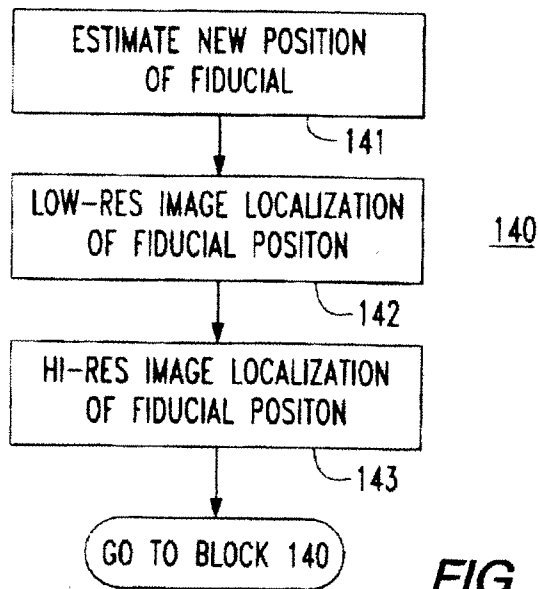
FIG. 10

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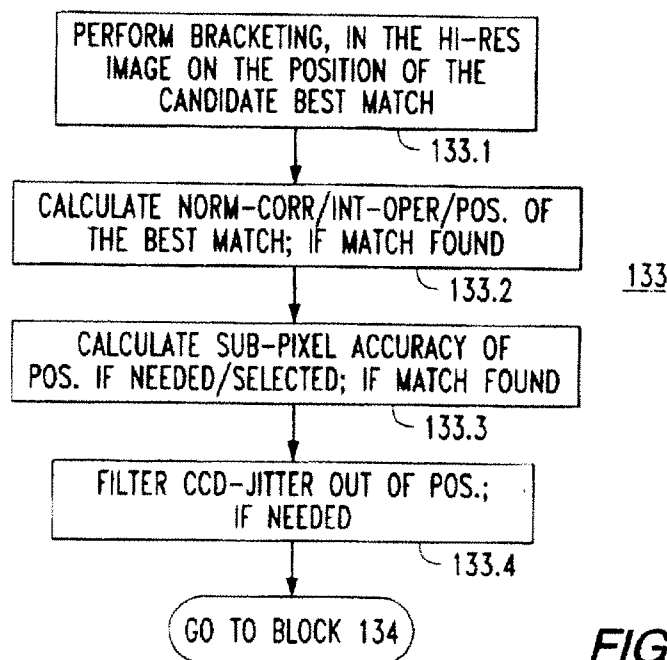
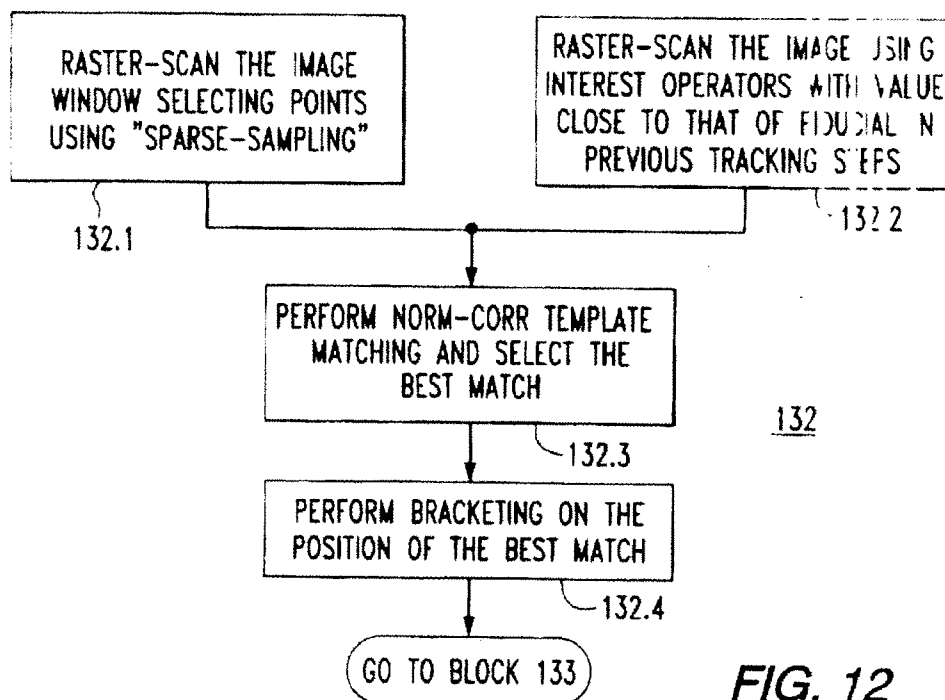


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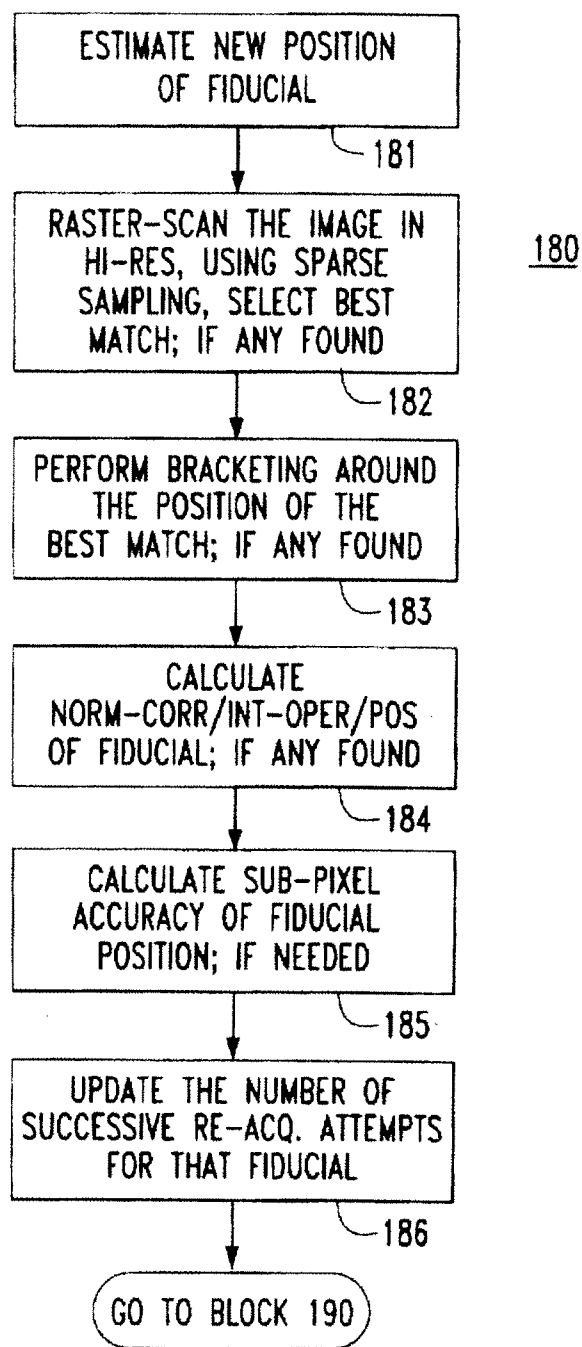


FIG. 15



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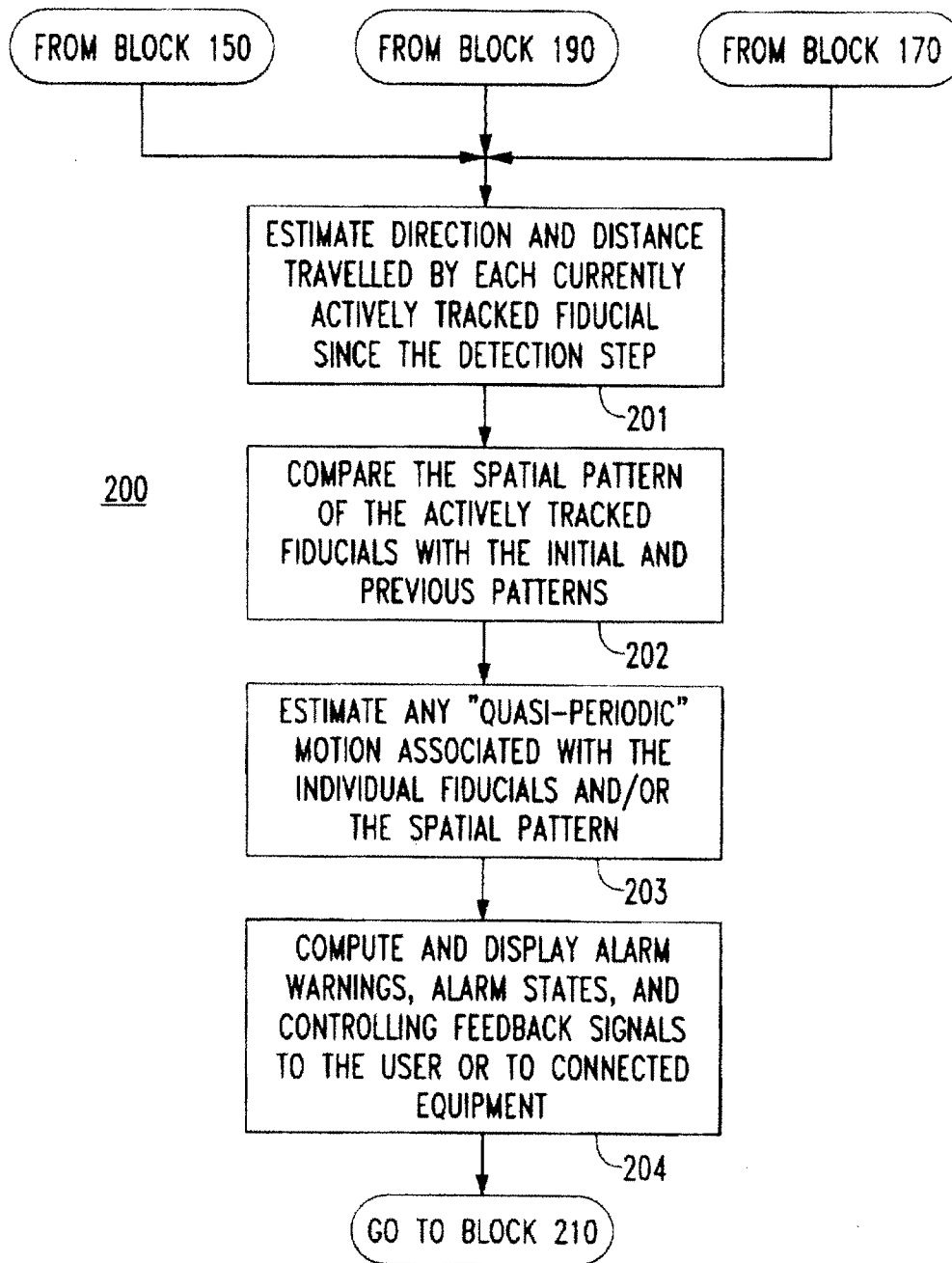


FIG. 16

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## APPARATUS RESPONSIVE TO MOVEMENT OF A PATIENT DURING TREATMENT/ DIAGNOSIS

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

This invention relates to medical use of radiation for treatment and diagnosis, and more particularly to detection and response to patient movement during radiological treatment and diagnosis.

#### 2. Background Information

Conventional radiotherapy treatment relies on simple patient setup techniques. These techniques use stationary and a limited number of radiation fields, which are often much wider than the tumor or volume, thus effectively compensating for the possibility of a tumor geometric miss. Consequently, a substantial amount of healthy tissue is irradiated and becomes a radio-biological dose limiting factor in tumor control.

Modern conformal dynamic radiotherapy attempts to overcome the above radio-biological limitation by tight-margin conformation of radiation dose distribution tailored to the three-dimensional tumor volume by the use of computer-control multibeam conformal dynamic radiotherapy (CCRT). Consequently, the accuracy in patient position, knowledge of the movement of a patient including substantial motion of internal organs such as with breathing is of primary importance. In addition to patient movement which would cause the tight beam to miss the tumor, it is important to be able to detect patient movement which could cause a collision between the patient and the linear accelerator, which is repeatedly repositioned to establish the multiple treatment beams.

There is a need therefore for apparatus for detecting patient movement on radiological treatments/diagnostic equipment.

There is a particular need for such apparatus which can detect submillimeter patient movement in real time.

There is also a need for such apparatus which can detect patient movement initiated from various treatment positions.

There is also a need for such apparatus which can detect patient movement under varying lighting conditions.

There is a further need for such apparatus which can discriminate movement associated with patient breathing from other movement and accommodate therefor.

### SUMMARY OF THE INVENTION

These needs and others are satisfied by the invention which is directed to apparatus responsive to movement of a patient which identifies and tracks movement of at least one passive fiducial on the patient. The apparatus applies multiple levels of filtering which can include: correlation, preferably normalized correlation, sparse sampling, bracketing and interpolation, and minima suppression to rapidly identify the location of the at least one fiducial. The multiple levels of filtering are applied at multiple levels of resolution of the digital image signals.

Interest operators can be used in combination with templates to locate the positions of the passive fiducials. The templates can be selected interactively by a user from a display generated by the digital image signals. Alternatively, the template used for tracking is selected from images generated using an initial template. Rather than using the image which best matches the initial template, the template with a median match is selected.

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As another aspect of the invention, the means generating an output includes means indicating movement of the at least one passive fiducial relative to at least one selected level of displacement. Preferably, the output means generates a warning that movement exceeds a first displacement and includes means providing a signal for terminating radiation treatment when the movement exceeds a second greater displacement. Preferably, the means providing an indication of movement includes a display generating an image of the patient and the fiducials, together with an indication of movement relative to the first and second displacements.

As yet another aspect of the invention, the means determining movement of the passive fiducials includes means detecting movement associated with patient breathing and random movement. The movement associated with patient breathing can be used to generate a gating signal synchronized to patient breathing. This gating signal can then be used to actuate the beam generator only during selected parts of the breathing cycle.

### BRIEF DESCRIPTION OF THE DRAWINGS

A full understanding of the invention can be gained from the following description of the preferred embodiments when read in conjunction with the accompanying drawings in which:

FIG. 1 is an isometric view of apparatus in accordance with the invention for implementing conformal dynamic radiotherapy.

FIG. 2 is a plan view of a patient reclining on a couch which forms part of the apparatus of FIG. 1 and illustrating the placement of fiducials in accordance with the invention.

FIG. 3 is a perspective view of a preferred fiducial used in implementation of the invention.

FIG. 4 is a functional diagram illustrating implementation of the invention.

FIG. 5 is an illustration of a display which is generated by the apparatus of FIG. 1 in implementation of the invention.

FIGS. 6-16 are flow charts of software used in implementation of the invention.

FIG. 17 is an illustration of an interest operator which can be used in implementation of the invention.

### DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 illustrates a radiotherapy treatment system 1 in which the invention is implemented. This system 1 includes a machine 3 having a gantry 5 pivotally mounted on a machine base 7 for rotation about a horizontal axis 9. The gantry 5 has a first arm 11 carrying a collimator 13 which directs a beam of high energy radiation 15, such as a beam of high energy photons, along a path which is perpendicular to and passes through an extension of the axis of rotation 9. This intersection is referred to as the isocenter 17. In some machines, a portal imager 19 is mounted on a second arm 21 on the opposite end of the gantry in alignment with the radiation beam 15. The portal imager 19 records radiation which is not absorbed by the patient.

The isocenter 17 serves as the origin of a coordinate system for room space. As can be seen, the X axis coincides with the axis of rotation 9 of the gantry. Thus, as the gantry 5 rotates it defines a plane of treatment containing the Y and Z axes.

The machine 3 further includes a patient positioning assembly 23, which includes a couch 25 mounted on a

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support 27 for vertical, lateral and longitudinal movement relative to the support. The support 27 is mounted on a turntable 29, which has its axis 31 vertically aligned under the isocenter 17 and concentric with the Z axis. With this arrangement, the patient positioning assembly 23 has four degrees of freedom: translation in the X, Y and Z axes of room space and rotation about the Z axis. Thus, the patient is not rotated about the longitudinal axis of the couch or tilted about a horizontal axis extending transversely through the couch. However, with the addition of rotation of the gantry in the Y-Z treatment plane, the radiation beam 15 can be directed through a patient reclining on the couch 25 in any desired direction. A computer 33 controls movement of the patient positioning assembly 23 and the gantry 5 for establishing the progression of high energy treatment beams used in practicing conformal radiation therapy.

As previously discussed, in conformal radiation therapy the beam 15 is tightly conformed by the collimator 13 to the specific tumor to be treated. Thus, movement of the patient on the couch 25 of the patient position assembly 23 can cause misalignment of the radiation beam 15 with the tumor. This not only degrades treatment of the tumor but also exposes surrounding healthy tissue to unwanted levels of radiation. In addition, normal breathing by the patient can cause movement of internal organs by an amount which would result in misalignment of the beam. For instance, a tumor on the lower portion of the lung can move several centimeters during normal breathing. Slight movement of the patient can be tolerated; however, treatment should be terminated if acceptable tolerances of movement are exceeded. Furthermore, excessive movement by the patient can also cause a collision between the patient and the gantry as the patient positioning assembly 23 and gantry are positioned for successive treatment beams.

The invention employs a vision system 34 to measure and respond to patient movement. The vision system 34 includes at least one video camera 35. Preferably, multiple cameras are used. In the exemplary embodiment of the invention a first camera 35<sub>1</sub> is mounted on the first arm 11 of the gantry 5 adjacent the collimator 13 and is aimed to capture an image of a patient 37 positioned on the couch 25, as shown in FIG. 2. As the camera 35<sub>1</sub> will be below the couch 25 for some positions of the gantry 5, a second camera 35<sub>2</sub> is fixed to the ceiling over the patient positioning assembly 23. The field of view of this camera 35<sub>2</sub> will be blocked when the gantry 5 is at the top of its arc. Thus, the patient is visible to at least one camera 35 at all times. Additional cameras 35 could be provided, such as cameras laterally displaced from the patient positioning assembly 23 to provide more sensitivity to movement along the axis of, for instance, the camera 35<sub>2</sub>. However, as will be discussed below, a single camera can detect three-dimensional movement, including movement toward and away from the camera which is detected as a change in the size of the image.

In the exemplary embodiment of the invention, natural or artificial fiducials are used to detect patient movement. Natural fiducials could be scars or other prominent features of the patient. The preferred fiducial 39 shown in FIG. 3 is a sphere 41 covered with a material having a lambertian surface. Such a surface is highly reflective under low light conditions, yet provides a uniform scattered reflection with no highlights. The sphere 41 is attached to the center of a non-reflective base 43 which is secured to the patient's skin, such as by an adhesive.

In principle, only one fiducial 39 is required. As a practical matter, it is advantageous to provide multiple fiducials placed on the patient so as to detect any movement of the

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critical locations. Thus, as shown in FIG. 2, by way of example, four fiducials 39 are placed on the patient's chest. Natural skin markings could be used in addition to the artificial fiducials shown in FIG. 3. If more than one camera 35 is used, each tracks as many of the fiducials 39 as it can see.

FIG. 4 is a functional diagram of the invention. The camera(s) 35 capture an image of the fiducials 39 on the patient 37 reclining on the patient positioning assembly 23. The image captured by the camera 35 is digitized by digitizer 45 to generate digital image signals. These digital image signals are 0 to 255 gray scale signals for each camera pixel. The digital image signals are processed by a processor which includes a patient motion detector 47. Patient motion detector 47 is implemented in the computer 49 shown in FIG. 1. The computer 49 includes a monitor 51 which generates a display 53, an example of which is shown in FIG. 5. The man machine interface 55 for the computer 49 includes a keyboard 57 and a pointing device 59, such as a mouse or trackball.

As will be discussed fully, the patient motion detector 47 detects and identifies the fiducials 39 and then tracks their movement. Movement within a certain narrow tolerance is acceptable, while larger movements are unacceptable. Visible and/or audio warnings of these two classifications of movement can be generated. A gating signal generator 61 responds to unacceptable movement to disable the beam generator 63. This unacceptable movement which would terminate the radiation beam can be movement which displaces the target tumor so that it is missed by the radiation beam, or could be movement which would cause a collision between the patient and the gantry 5 during movement of the machine from one treatment beam to the next. In the former case, the gating signal generator 61 could re-enable the beam generator, if the patient returns to the proper position. For instance, a large sigh could temporarily displace the target area by an unacceptable amount. In accordance with another aspect of the invention, the patient motion detector 47 can track patient breathing and extract such quasi-periodic motion from random patient motion. Gating of the beam generator can then be synchronized with patient breathing. For instance, a tumor on the lung could move up to 4 to 5 centimeters during patient breathing. This is an unacceptable amount of movement. However, by synchronizing generation of the radiation beam with breathing, the tumor can be repetitively irradiated at a fixed position during the breathing cycle.

As shown in FIG. 5, the display 53 presents an image of the patient 37 with the fiducials 39 appearing prominently. An indicator 65, such as the square shown, surrounds each fiducial and is color coded to indicate the state of motion of the fiducial. The fiducial with the largest displacement such as 39a is singled out by a distinctive marker, such as a red square 65a, while the remaining markers are green squares in the exemplary system. The display also includes a traffic light 67 having a green section 67g, a yellow section 67y and a red section 67r. When motion of the fiducials is within preferred tolerances, the green section 67g of the traffic light is on. For motion which is outside the normal range, but which is still acceptable, the yellow section 67y is on. The traffic light turns red when the motion of any of the fiducials is approaching the unacceptable. A scale 69 along the side of the display 53 indicates in bar graph form the percentage of maximum allowable displacement of the fiducial of maximum displacement. Thus, for instance, if the red light 67r is illuminated and the bar graph 71 indicates 80%, the fiducial with maximum displacement has moved by a distance which

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is four fifths of the way through the acceptable displacement. The green, yellow and red regions need not be equal as shown in the example.

Detection of motion of a patient using passive fiducials requires an implementation which is robust enough to accommodate for the variations in the shapes, appearance and lighting conditions to which the fiducials are subjected and, at the same time, is fast enough to provide real time tracking of patient movement. The invention satisfies these requirements by utilization of successive levels of filtering and templates which are modified to accommodate for actual conditions. The result is a system which can track patient movement at 20 Hz or better.

Flow charts of suitable software 100 for implementing the invention are illustrated in FIGS. 6-16. FIG. 6 illustrates the main routine of the software 100 and includes detecting fiducials on the patient's body in the current camera image at 110. As will be described, this is accomplished utilizing templates. The templates are then fine tuned at 120 for the specific patient and environmental conditions. As long as the user desires monitoring as determined at 130, a loop is entered in which each individual fiducial is tracked as indicated at 140. It is possible that a fiducial can be lost by the tracking system. This could occur, for instance, if the patient moves so that a fiducial is blocked from the camera's view, or the patient moves a hand through the line of sight of the camera. Also, a fiducial may be temporarily lost by rapid movement or adverse lighting conditions. If a fiducial is lost, as determined at 150, a number of attempts can be made to reacquire it. If the fiducial is not reacquired within a reasonable time, however, it is removed from tracking as indicated by 160 and 170. If the selected number of attempts to reacquire, such as for example, five, have not been reached, an attempt is made to reacquire the fiducial at 180. If the fiducial is reacquired at 190, then a routine is run at 200 to generate any alarm if needed, and gating signals for the accelerator or beam generator 63 as indicated at 200. As long as any fiducials remain to be tracked as indicated at 210, the tracking loop is repetitively run.

FIG. 7 illustrates the general routine 110 for detecting the fiducials 39 in the image represented by the digital image signals. As mentioned, templates are used to identify the locations of the fiducials. The templates indicate what the pattern of digital signals representing the fiducial should look like. The size of the templates used must be considered. Larger templates improve the accuracy but take longer to process. In the exemplary system, templates 40 pixels square have been utilized. There are several ways in which the templates can be generated. As indicated at 111 in FIG. 7, idealized image templates can be utilized. In addition to such idealized templates or in place thereof, pre-stored image templates for the patient can be used as indicated at 112. Such pre-stored templates are used, for instance, for natural fiducials such as scars. One template is used for each family of fiducials. For instance, if all of the fiducials are the preferred fiducials such as shown in FIG. 3, only one template is required because all of the fiducials in the family will generate a similar image.

In addition, templates can be selected interactively by the user at 113. This is accomplished by using the mouse or trackball 59 to click on the center of a representation of the fiducial on the display 53.

Where the idealized or pre-stored templates are utilized, a multiresolution pyramid is used to locate the fiducials in the image using the templates. Thus, as indicated at 114, a search is made of the current image in low resolution for

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candidate matches of all template families. In the exemplary embodiment of the invention, one-third resolution is used at this point. Matches are made using a normalized correlation between the template and the image. The matches found in low resolution are then verified and localized in high resolution at 115. The K best matches are then selected as the most reliable fiducials at 116 where K equals the number of fiducials to be tracked. The user is then given the opportunity at 117 to edit the detected location of fiducials found either through use of the idealized or pre-stored templates or templates generated interactively.

The details of the low resolution detection routine performed in block 114 of FIG. 7 is shown in FIG. 8. As shown at 114.1, the image can be raster scanned selecting points using sparse sampling. In raster scanning pixels are considered successively along each line, line-by-line in increments of one, while in sparse sampling the increment is greater than one. Alternatively, the image can be raster scanned as indicated at 114.2, selecting candidate points using interest operators followed by thresholding. Interest operators are simple patterns which emphasize gray scale characteristics of a particular fiducial. An example is shown in FIG. 17, where the fiducial is a light circle 73 on a dark background 75. The interest operator 77 could be, for instance, the one pixel value 79 in the center having a gray scale value matching that of the light circle 73, and the four pixels 81 at the cardinal points having gray scale values similar to that of the background 75. Such interest operators permit rapid searching of the image and should be selected as to assure identifying all of the fiducials in the family. They will most likely also generate additional candidate points. Returning to FIG. 8, the interest operator generated value in the exemplary system is the relative albedo. The relative albedo of each point in the low resolution scan is compared to a threshold value to select candidate points.

For each candidate point, a template matching is performed at 114.3, using a normalized correlation. Unwanted point matches are then filtered out at 114.4 using thresholding on the normalized correlation value. In the exemplary embodiment, a normalized correlation of 0.75 was used as the threshold. Bracketing and interpolation are then used at 114.5 to localize the remaining point/matches. In implementing bracketing, a rectangular image window is selected within which the desired point match will definitely lie. Then by interpolating between the correlation values of points on the border of the selected window along with its center, a new estimate of the location of the point match is calculated. This process is repeated with successively smaller windows centered on the new estimate of the location of the point match until a singular point is reached. In the exemplary system, the interpolation is performed using a two-dimensional Gaussian distribution.

FIG. 9 illustrates the techniques for verifying the candidate matches in high-resolution indicated at 115 in FIG. 7. Bracketing is performed on the selected matches in high resolution as indicated at 115.1. These points are then filtered at 115.2 within the same image neighborhood using minima suppression. In implementing minima suppression, for each point which has been a match, an area the size of the template is centered on the point. A point is selected as a further candidate match only if it is the best correlation with the template within the template window.

An important aspect of the invention is the fine tuning of the tracking templates called for at 120 in FIG. 6. FIG. 10 illustrates the details of fine tuning the templates. As indicated at 121, the median point/match from fiducials detected using the same initial template is selected. For example, if



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there are three point matches for a fiducial family, the match having the middle value of correlation is selected. Notice that the match with the best correlation is not selected as it is likely to eliminate some valid matches. This technique adapts the selection of the template to be used for tracking to the actual conditions existing at the time of the selection. The relevant image portion is then acquired as the new template at 122, and the position, the interest operator value and the normalized correlation for all relevant point/matches using this newly acquired template is then recorded at 123. The steps 121-123 are accomplished for each template family. Then, the current special pattern of all the fiducials determined by the point/matches, is recorded at 124.

The program then enters the tracking loop at block 130 in FIG. 6. The routine for continuous tracking, which is called at 140 in FIG. 6 is illustrated in FIG. 11. The new position of the fiducial is estimated at 131 by projecting a velocity vector calculated from prior positions of the fiducial. Localization of fiducial position is then implemented in low resolution using bracketing and interpolation as indicated at 132. This is followed by high resolution localization of the fiducial position at 133, also using bracketing and interpolation.

The low resolution localization of block 131 is implemented by the routine illustrated in FIG. 12. As indicated at 132.1 points are selected by raster scanning the image window using sparse sampling. If interest operators are used, the interest operators with the value closest to that of the fiducial in the previous tracking step is selected at 132.2. In either case, a best match is selected using normalized correlation template matching at 132.3. This is followed by bracketing on the position of the best match at 132.4.

FIG. 13 illustrates the high resolution localization of fiducials called for in block 133 of FIG. 11. As indicated, bracketing is performed on a candidate with best match in high resolution as indicated at 133.1. If a match is found, the normalized correlation, interest operator value and position of the best match are calculated at 133.2. If desired, the sub-pixel accuracy of the position can be calculated at 133.3. The same interpolation technique as in bracketing and interpolation, as described above, is used. Alternatively, bilinear interpolation between the surrounding pixel correlation values could be used. Finally, if needed, charge coupled device (CCD) jitter is filtered out of the position at 133.4. In the exemplary system, a low pass filter is used.

The lost fiducial routine 150 in FIG. 6 is shown in FIG. 14. If the tracking routine finds no fiducial within the specified image window at 151, then clearly the fiducial has been lost. Even if a fiducial has been found, confirmation must be made that it is in fact the new position of the fiducial. Hence, a number of constancy tests are applied in 152. For instance, the normalized correlation value and the interest operator value must not change by more than a selected amount, such as, for example, 15%, from the most current values. Also, image limits are applied. For instance, the fiducial should not have changed position by more than a predetermined amount or, if the edge of the image is reached, the position indicated is not accepted as the fiducial may be out of the field of view, although a continued indication that it is at the edge may be presented.

The routine 180 in FIG. 6 for reacquiring the lost fiducial is shown in FIG. 15. First, the new position of the fiducial is estimated at 181 using a larger search window than was used at 141 in FIG. 11. The image window is then raster scanned in high resolution using sparse sampling to select the best match, if any, at 182. Bracketing is then performed

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around the position of the best match, if any, at 183. The normalized correlation interest operator albedo and the position of the fiducial best matched is then determined at 184. This is followed by calculation of sub-pixel accuracy, if needed, at 185. Finally, the number of successive attempts to reacquire the fiducial is updated at 186.

FIG. 16 illustrates the routine 200 in FIG. 6 for generating the alarms and gating the accelerator or beam generator. The direction and distance traveled by each currently actively tracked fiducial since the detection step is estimated at 201. The special pattern of the actively tracked fiducials is compared with the initial pattern and previous patterns at 202. Any quasi-periodic motion associated with the individual fiducials and/or the special pattern is predicted at 203 such as by using past data analysis. This would include movement associated with breathing or tremor of the patient. The alarm warnings, alarm states and accelerator gating signals are then computed at 204 for display or for feedback to the equipment, such as the accelerator.

While specific embodiments of the invention have been described in detail, it will be appreciated by those skilled in the art that various modifications and alternatives to those details could be developed in light of the overall teachings of the disclosure. Accordingly, the particular arrangements disclosed are meant to be illustrative only and not limiting as to the scope of invention which is to be given the full breadth of the claims appended and any and all equivalents thereof.

What is claimed is:

1. Apparatus responsive to movement of a patient positioned on a patient positioning assembly during treatment/diagnosis, said apparatus comprising:

camera means generating digital image signals representing an image of at least one passive fiducial having a lambertian surface on said patient; and

processing means comprising means responsive to actual shape, appearance and lighting conditions of said at least one passive fiducial having a lambertian surface in said image represented by said digital image signals to determine successive positions of said at least one passive fiducial having a lambertian surface, means repetitively determining movement of said at least one passive fiducial having a lambertian surface from said successive positions, and means generating an output in response to predetermined values of said movement.

2. Apparatus responsive to movement of a patient positioned on a patient positioning assembly during treatment/diagnosis, said apparatus comprising:

a single camera generating digital image signals representing an image of at least one fiducial on said patient; and

processing means comprising means responsive to actual shape, appearance and lighting conditions of said at least one fiducial in said image represented by said digital image signals to determine successive positions of said at least one fiducial, means tracking three-dimensional movement of said at least one fiducial from said successive positions and means generating an output in response to predetermined values of said movement.

3. The apparatus of claim 2, wherein said means repetitively determining movement of said at least one fiducial includes means detecting movement associated with patient breathing, and said output means comprises means generating a gating signal synchronized to said patient breathing.

4. The apparatus of claim 2, wherein said processing means comprises means repetitively applying multiple lev-

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els of filtering to said digital image signals to determine successive positions of said at least one fiducial.

5. The apparatus of claim 4, wherein said means applying multiple levels of filtering includes means applying bracketing and interpolation to said digital image signals to determine position of said at least one fiducial.

6. The apparatus of claim 4, wherein said means applying multiple levels of filtering includes means applying minima suppression to said digital image signals.

7. The apparatus of claim 4, wherein said means applying multiple levels of filtering include means applying at least two types of filtering selected from a group consisting of correlation, sparse sampling, bracketing and interpolation, and minima suppression.

8. The apparatus of claim 7, wherein said processing means includes means using multiple levels of resolution of said digital image signals to determine successive positions of at least one fiducial and said means applying multiple levels of filtering comprise means applying filtering at each of said multiple levels of resolution.

9. The apparatus of claim 4, wherein said processing means includes means using at least one of templates and interest operators to determine successive positions of said at least one fiducial from said digital image signals.

10. The apparatus of claim 2, wherein said pressing means comprises means using a template to successively determine position of said at least one fiducial and means selecting said template.

11. The apparatus of claim 10, wherein said at least one fiducial comprises a plurality of fiducials, and said means selecting a template includes means generating an initial template, means generating template matches for each of said plurality of fiducials from said digital image signals using said initial template, and means selecting one of said template matches for use in determining positions of each of said plurality of fiducials.

12. The apparatus of claim 11, wherein said means selecting said one of said template matches includes means generating a value for each of said templates matches, and means selecting a template match having a median value as said one template match.

13. Apparatus responsive to movement of a patient positioned on a patient positioning assembly during treatment/diagnosis, said apparatus comprising:

camera means generating digital image signals representing an image of at least one fiducial on said patient; and

processing means comprising means responsive to actual shape, appearance and lighting conditions of said at least one fiducial in said image represented by said digital image signals to determine successive positions of said at least one fiducial at a rate of at least 20 Hz, means tracking movement of said at least one fiducial from said successive positions, and means generating an output in response to predetermined values of said movement.

14. The apparatus of claim 13, wherein said means generating an output includes means generating an indication of movement relative to at least one selected level of displacement.

15. The apparatus of claim 14, wherein said means generating said indication of movement includes means providing a warning that said movement exceeds a first displacement and means providing a signal for terminating

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radiation treatment/diagnosis when said movement exceeds a second displacement greater than said first displacement.

16. The apparatus of claim 14, wherein said means generating an indication of movement comprises display means generating an image of said fiducials and an indication of said movement relative to said first and second displacements.

17. The apparatus of claim 16, wherein said camera means includes means generating digital image signals for a plurality of fiducials, said means repetitively determining movement determines movement of each of said plurality of fiducials, and said display means includes indicator means indicating a fiducial with the greatest movement.

18. The apparatus of claim 14, wherein said means repetitively determining movement includes means detecting movement associated with patient breathing and random movement, and wherein said means generating an indication of movement indicates said random movement.

19. Apparatus responsive to movement of a patient positioned on a patient positioning assembly during treatment/diagnosis, said apparatus comprising:

camera means generating digital image signals representing an image of at least one fiducial on said patient; and

processing means comprising means responsive to actual shape, appearance and lighting conditions of said at least one fiducial in said image represented by said digital image signals to determine successive positions of said at least one fiducial, means repetitively determining movement of said at least one fiducial from said successive positions, and means generating an output in response to predetermined values of said movement;

said processing means further comprising means using a template to successively determine position of said at least one fiducial and means selecting said template comprising display means, means generating on said display means an image of said at least one fiducial from said digital image signals and user interface means for selection of a template from said image of said at least one fiducial.

20. Apparatus responsive to movement of a patient positioned on a patient positioning assembly, said apparatus comprising:

camera means generating digital image signals representative of an image of said patient; and

processing means comprising means determining movement of said patient from said digital image signals, including movement associated with breathing by said patient, and gating means generating gating signals synchronized with said movement associated with breathing by said patient.

21. The apparatus of claim 20, wherein said camera means generates said digital image signals representing an image of at least one fiducial on said patient, and said means determining movement of said patient includes means determining movement of said at least one fiducial.

22. The apparatus of claim 20 adapted for use during treatment of said patient with a radiation beam generated by a beam generator, wherein said gating means comprises means generating said gating signals synchronized to actuate said beam generator in synchronism with patient breathing.

\* \* \* \* \*

**EXHIBIT B**



US005784431A

**United States Patent** [19]  
**Kalend et al.**

[11] **Patent Number:** 5,784,431  
[45] **Date of Patent:** Jul. 21, 1998

[54] **APPARATUS FOR MATCHING X-RAY IMAGES WITH REFERENCE IMAGES**

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[73] **Assignee:** University of Pittsburgh of the Commonwealth System of Higher Education, Pittsburgh, Pa.

[21] **Appl. No.:** 739,622

[22] **Filed:** Oct. 29, 1996

[51] **Int. Cl.<sup>6</sup>** ..... A61N 5/10

[52] **U.S. Cl.** ..... 378/65; 378/69; 378/901

[58] **Field of Search** ..... 378/8, 20, 65, 378/68, 69, 901

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**Primary Examiner**—David P. Porta

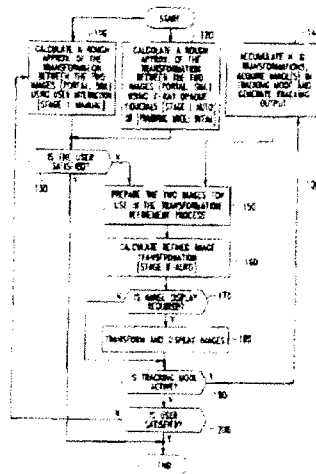
**Assistant Examiner**—David Vernon Bruce

**Attorney, Agent, or Firm**—Richard V. Westerhoff; Eckert Seamans Cherin & Mellot, LLC

[57] **ABSTRACT**

X-ray images such as radiotherapy portal images and simulation images are matched by apparatus which digitizes the images and automatically processes the digitized signals to generate matched digitized signals which can be displayed for comparison. The digitized images are first coarse aligned using a transform generated from seed points selected interactively from the two images or through detection and identification of x-ray opaque fiducials placed on the patient. A fine alignment is then performed by first selecting intersecting regions of the two images and enhancing those regions. Secondly, an updated transform is generated using robust motion flow in these regions at successive ascending levels of resolution. The updated transform is then used to align the images which are displayed for comparison. The updated transform can also be used to control the radiotherapy equipment.

28 Claims, 8 Drawing Sheets



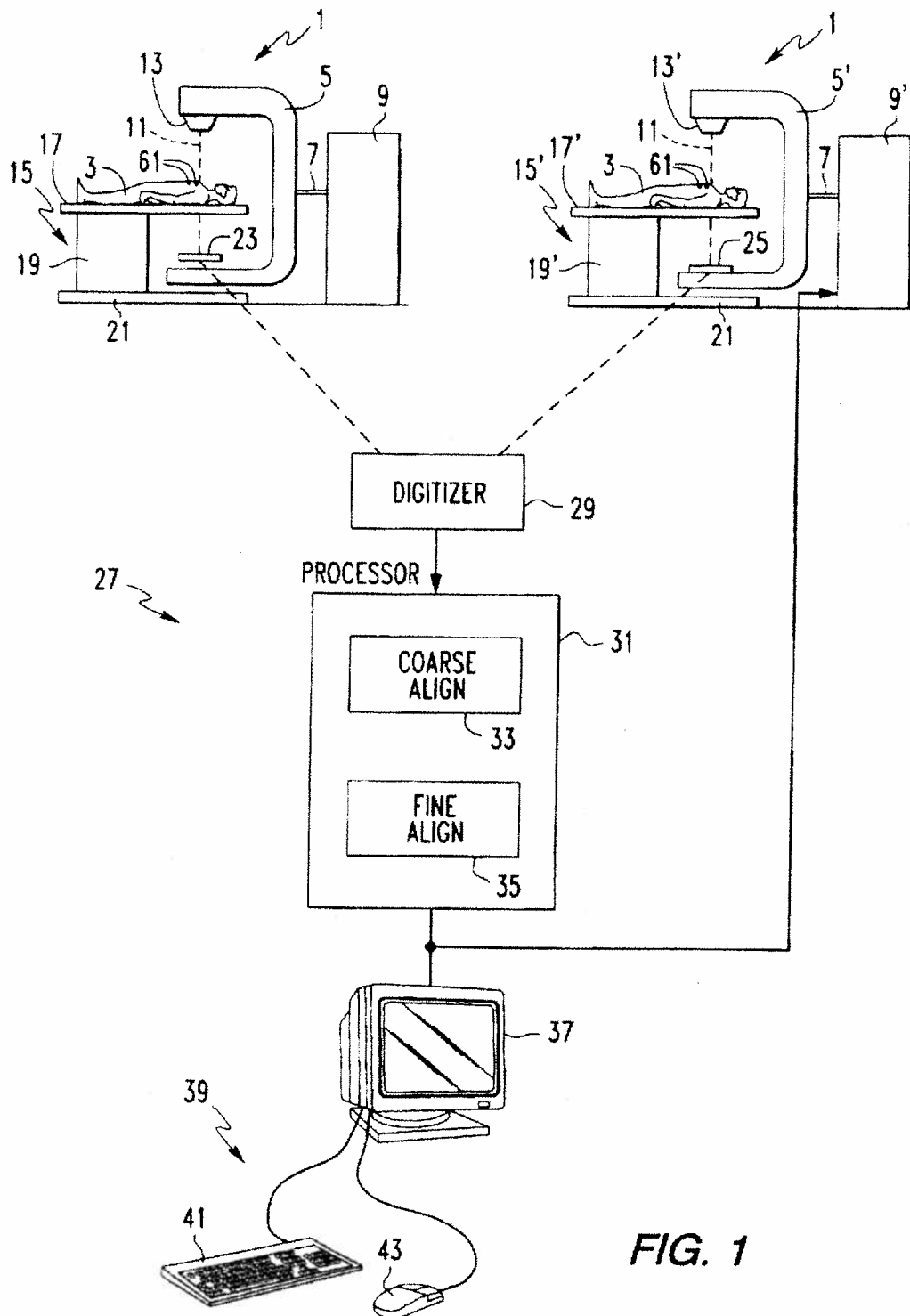


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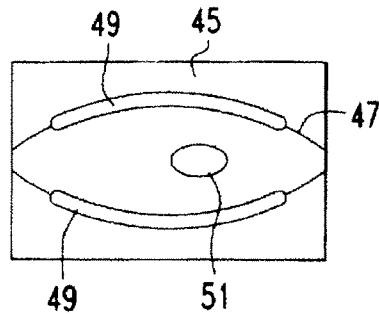


FIG. 2a

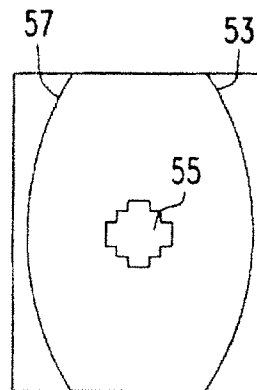


FIG. 2b

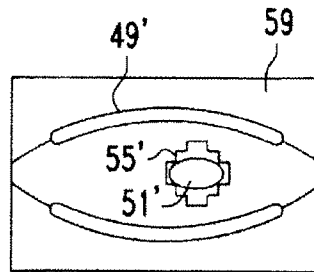


FIG. 2c

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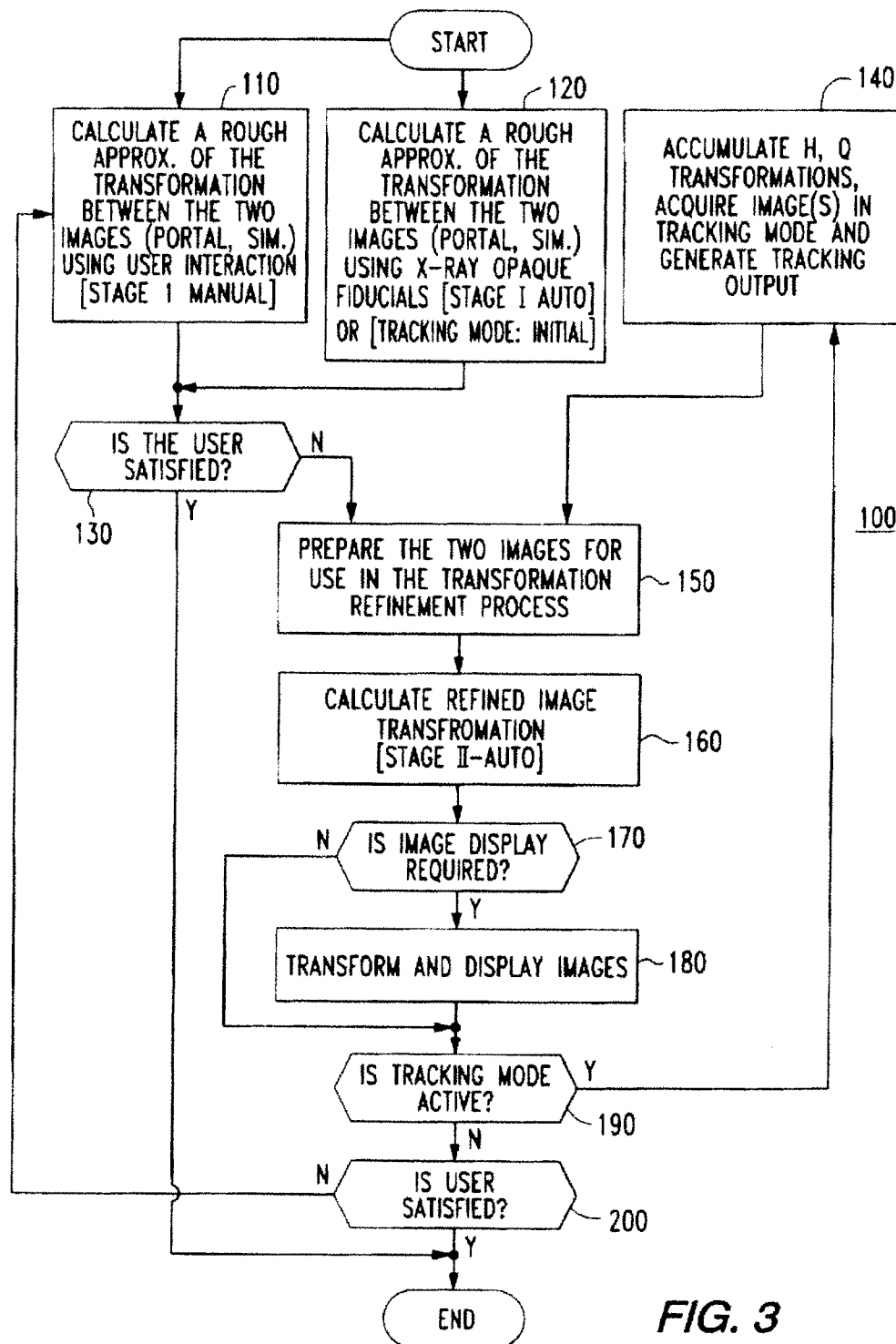


FIG. 3

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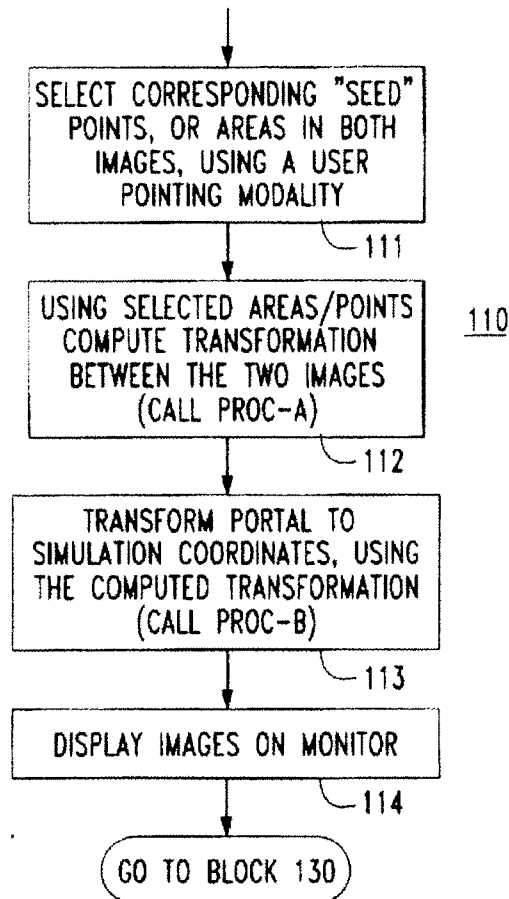


FIG. 4

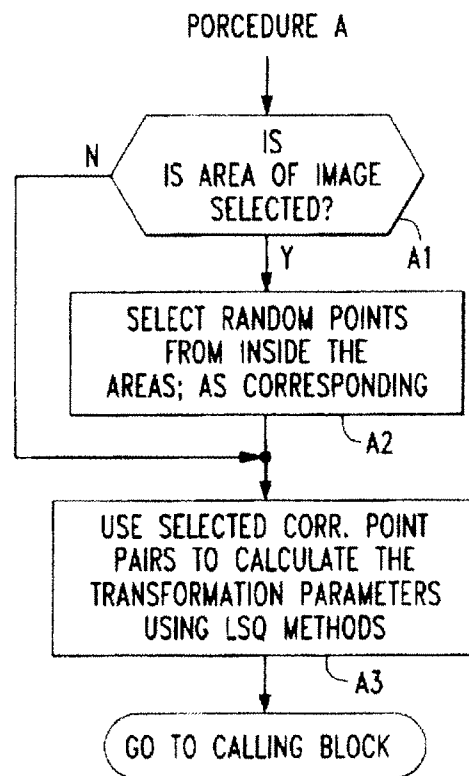


FIG. 5

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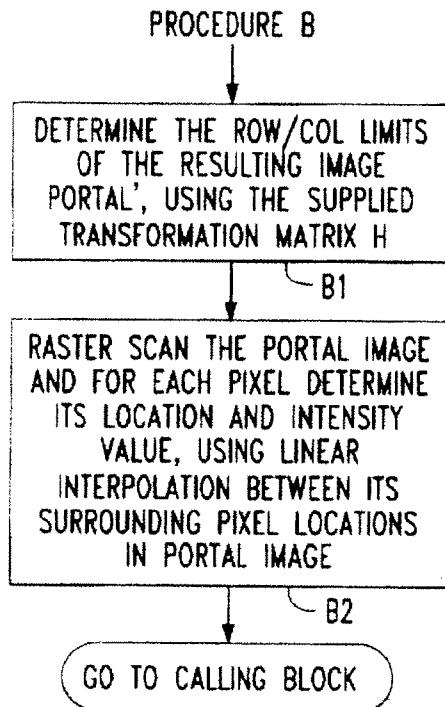


FIG. 6

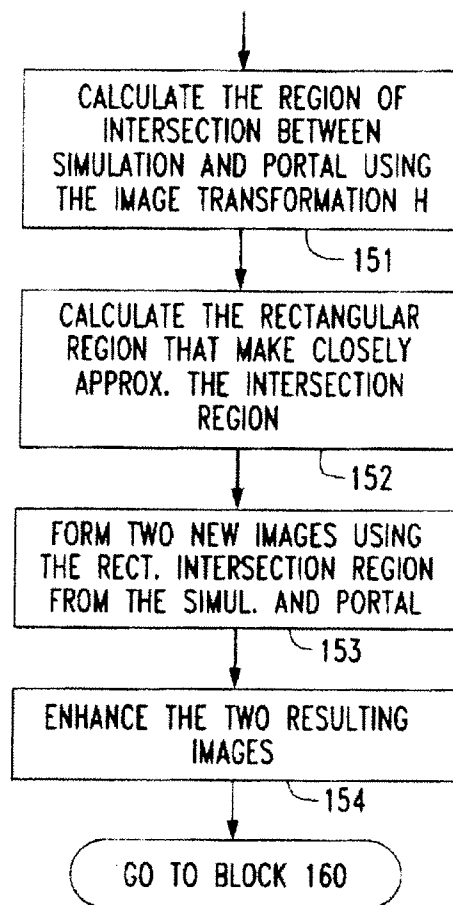


FIG. 8

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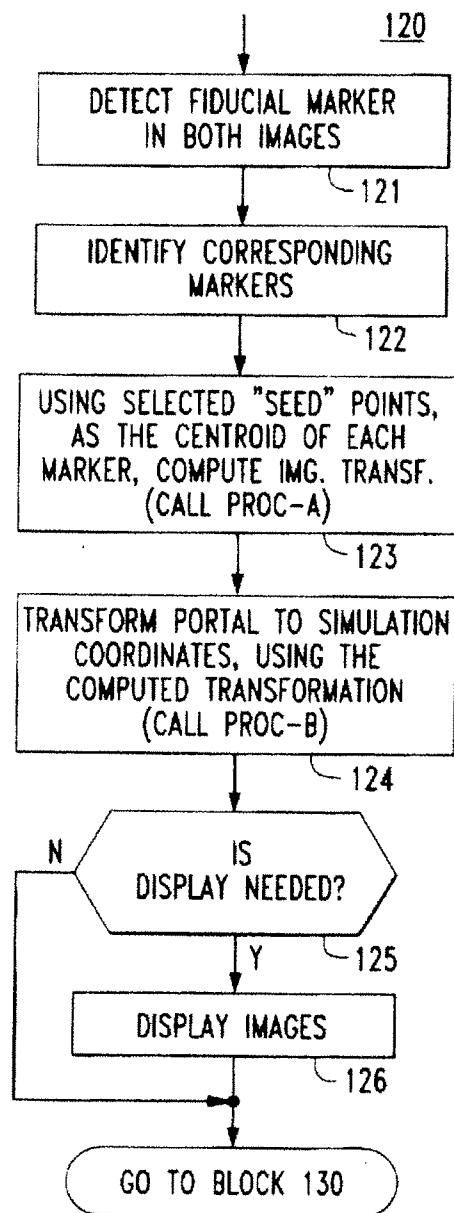


FIG. 7

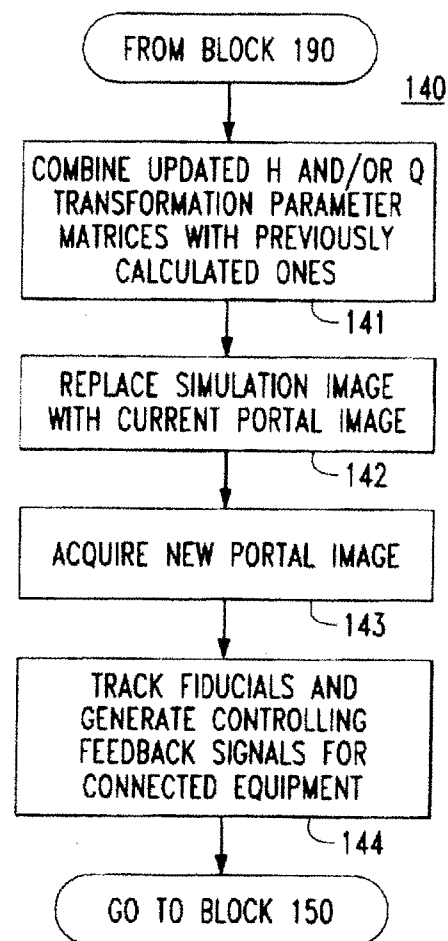


FIG. 11

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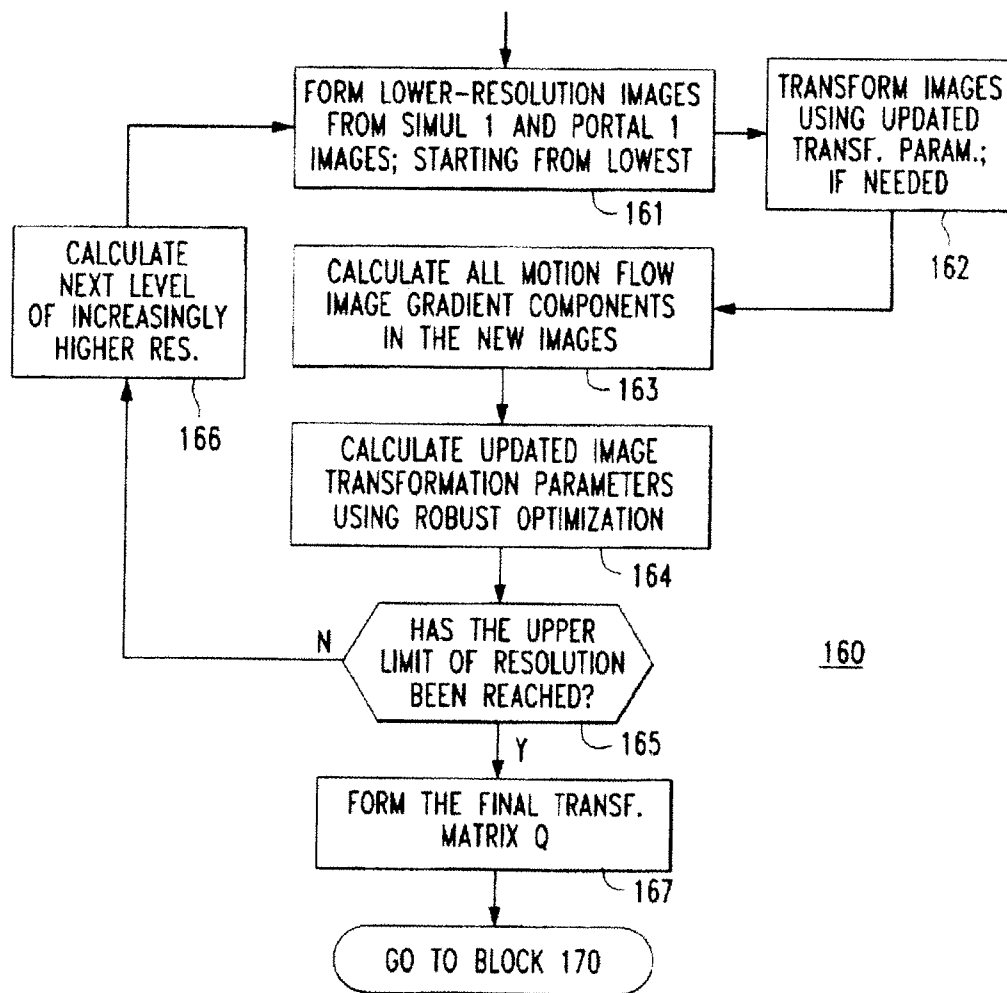


FIG. 9

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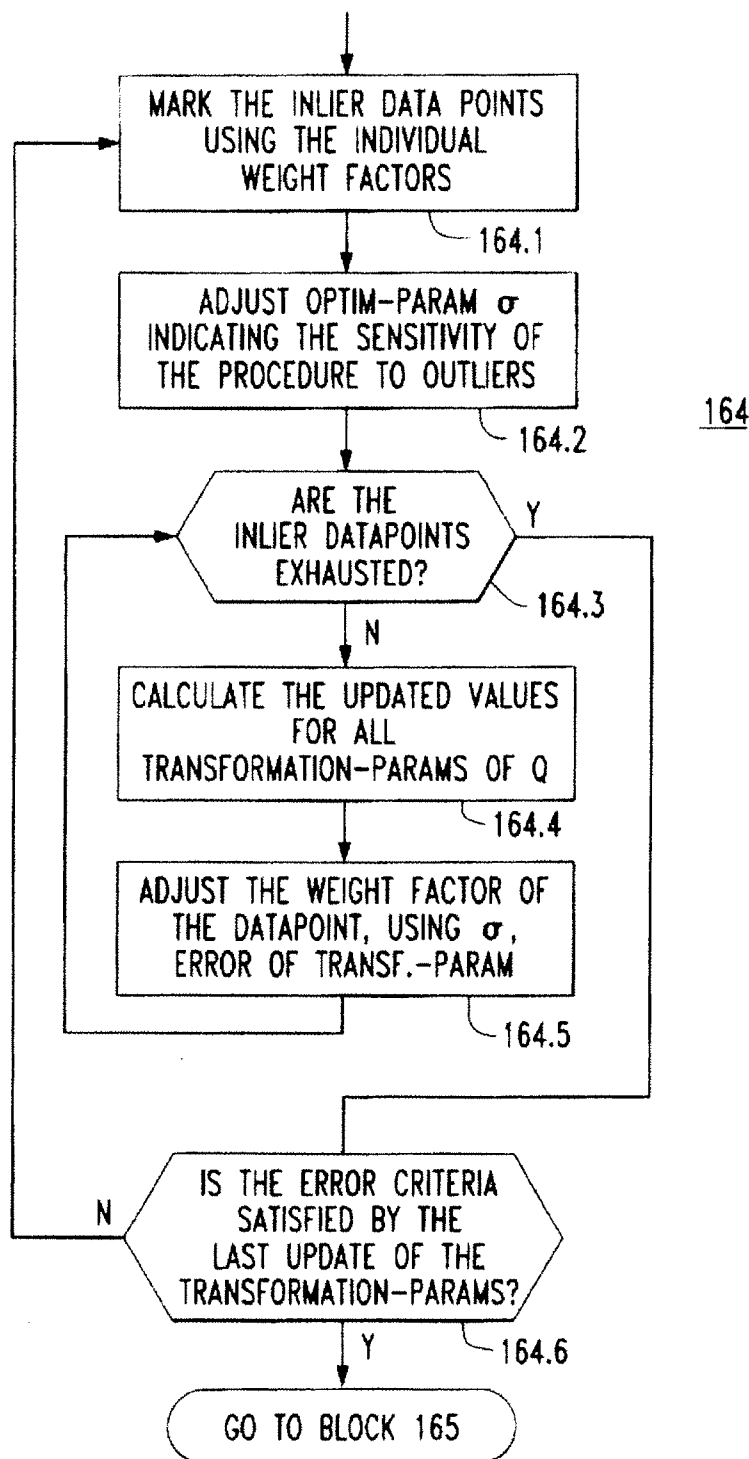


FIG. 10



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## APPARATUS FOR MATCHING X-RAY IMAGES WITH REFERENCE IMAGES

### BACKGROUND OF THE INVENTION

#### 1. Field of the Invention

This invention relates to matching similar x-ray images and has particular application to computer controlled radiotherapy apparatus for automatically matching on-line the portal images generated during radiotherapy treatment on a treatment machine with simulation images generated prior to treatment on a simulation machine for determining that the desired target is actually being irradiated for the purposes of assessment, and/or controlling the treatment equipment.

#### 2. Background Information

There are medical applications which require matching of x-ray images. For instance, in computer controlled radiotherapy, treatment beams of high energy radiation are directed at a tumor from a number of directions so as to maximize irradiation of the tumor while minimizing exposure of healthy tissue surrounding the tumor. Such radiotherapy treatment typically has two distinct phases: the simulation phase, and the actual treatment phase. In the simulation phase, the patient is placed on equipment similar to the treatment equipment except that it does not generate the high energy radiation beam. The simulation equipment is successively positioned to simulate the delivery of the sequence of treatment beams prescribed by the treating oncologist. This assures that the equipment can be positioned to deliver the required treatment beams and progressively move from one treatment beam to the next without collision between the equipment and the patient or between movable components of the equipment. During this procedure a low dosage x-ray image called the simulation image is taken. This simulation image, which generally has good contrast and detail because of the low energy of the x-ray beam used (in the kiloelectronvolt range) helps the oncologist to locate the position of the tumor and thereby establish the positions of the equipment components for delivering the successive treatment beams.

During the actual treatment phase, the patient is placed in the exact same position on the equipment as in the simulation before the regular-dosage x-ray radiation, typically in the megaelectronvolt range, is used to treat the patient. During this phase, another x-ray image is taken, which is called the portal image.

After completion of the treatment, the simulation and portal images are compared by an expert to determine whether the tumor, as identified in the simulation image, has been adequately treated with radiation in the portal image. If the coverage is not complete, the patient is scheduled for a corrective treatment.

The current accepted procedure involves the manual comparison of the portal and simulation images. Accurate manual comparison is quite challenging given the fact that the two x-rays are usually taken by different equipment and at different levels of radiation exposure. The latter fact implies that the tumor area is usually not visible in the portal x-ray, and thus the matching of the portal image with that of the simulation has to rely on manual estimation of dimensions from anatomical landmarks, which will not be clearly visible.

Conventionally, the portal images have been generated by using x-ray film which has to be developed. This is not a serious drawback where only a single or a few treatment beams are utilized. However, this x-ray film is a serious

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limitation in computer controlled radiotherapy where a large number of treatment beams are used. Electronic portal imagers have been developed which generate a digitized image which can be displayed on an electronic display device. Unfortunately, the same problems exist as to the contrast and definition in the portal image generated electronically.

The problem of matching portal images with simulation images is compounded by the fact that the images have differences in orientation caused by skewing, scaling differences, rotation, translation and differences in perspective and curvature.

In stereotactic radiology, digitized computed tomography x-ray images and magnetic resonance images (MRI) have been automatically matched by applying scaling derived from known fixed dimensions of a steel frame which appears in both images. Such fixed landmarks of known dimensions are not available in conventional radiotherapy images.

There is a need, therefore, for apparatus for automatically matching x-ray images and particularly for matching portal images with simulation images in radiotherapy.

There is also a need for such apparatus which can match the portal and simulation images on-line for multiple treatment beams.

There is further need for such apparatus which can match portal images and simulation images having widely different contrast and definition and differences caused by skewing, rotation, scaling, perspective or curvature.

There is an additional need for apparatus for obtaining and maintaining alignment of a patient during computed controlled radiotherapy or for terminating the radiation beam if alignment becomes unacceptable.

### SUMMARY OF THE INVENTION

These needs and others are satisfied by the invention which is directed to apparatus for automatically matching an x-ray image with a reference image, and particularly for matching the portal image with a simulation image for determining whether radiotherapy treatment has been adequate or for matching successive portal images for controlling operation of the radiotherapy equipment. In matching images, digitizing means digitizes the x-ray image such as the portal image to generate a first set of digital image signals or digital portal image signals (DPIS) in the case of the portal image. The digitizing means also digitizes the reference image such as the simulation image to generate second digital image signals or digital simulation signals (DSIS). Processing means process these digital image signals to generate matched digital image signals. The processing is performed without any prior knowledge of the physical dimensions of any of the features in the images. Output means generate for instance a display from the matched digital image signals and/or control the treatment/diagnosis equipment.

The processing means includes coarse alignment means which first effect a coarse alignment between the digital portal image signals and the digital simulation image signals. Coarse alignment is initiated by selecting seed points in the portal image represented by the DPIS and in the simulation image represented by the DSIS. Selection of the seed points can be done either interactively using a pointing device such as a mouse to select what appear to be corresponding points on displays of the two images, or automatically through use of x-ray opaque fiducials placed on the patient. In either case, the seed points are used to compute a transform between the two images. Means are then used to

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apply the transform to one of the sets of digital image signals to transform points in that image to the coordinates of the other image thereby producing coarse aligned DPIS and DSIS.

Following coarse alignment, a fine alignment is performed. In implementing the fine alignment, the coarse aligned DPIS and DSIS are first prepared by selecting selected DPIS and selected DSIS for regions of the images which intersect or overlap, and preferably for a region of regular shape such as a rectangle within the intersecting regions of the images. The digital image signals for these regions are then enhanced to produce prepared images with similar dynamic range and pixel intensities. The fine alignment means includes means generating an updated transform from the prepared DPIS and DSIS, and means applying the updated transform to either the coarse or prepared DPIS and DSIS to generate the matched DPIS and DSIS.

The means generating the updated transform comprises means generating motion flow components from the prepared DPIS and DSIS and calculating means calculating the updated transform from the motion flow components. Preferably the means generating the motion flow components generates motion flow gradient components and the calculating means comprises means applying a robust optimization to calculate the updated transform. The means generating updated transform uses successive ascending levels of resolution of the prepared DPIS and DSIS to generate the updated transform.

In the tracking mode, the updated transform is used to track movement between successive sets of digital portal image signals. Tracking can be used to terminate the radiation if patient movement exceeds specified limits, or could be used to operate the patient positioning assembly to maintain the radiation beam in proper alignment with the area to be treated.

The invention can also be used to match x-ray images with other reference images which could be another x-ray image or another type of image.

#### BRIEF DESCRIPTION OF THE DRAWINGS

A full understanding of the invention can be gained from the following description of the preferred embodiments when read in conjunction with the accompanying drawings in which:

FIG. 1 is a schematic diagram of apparatus for implementing the invention.

FIG. 2a is a simplified illustration of a simulation image to which the invention can be applied.

FIG. 2b is a simplified illustration of a portal image to which the invention may be applied.

FIG. 2c is a simplified illustration of a display superimposing the simulation and portal images of FIGS. 2a and 2b utilizing the invention.

FIGS. 3-11 are flow charts of software utilized to implement the invention in the apparatus of FIG. 1.

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

The invention is directed to matching x-ray images with reference images and will be described as applied to matching portal images generated in computer controlled radiotherapy with simulation images. However, it will be understood that the invention has wide application in matching other x-ray images such as those used in diagnosis, for example. As will be seen, the invention also has application

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for tracking motion in successive portal images such as for controlling positioning of a patient or gating of the radiation beam.

Referring to FIG. 1, a simulation setup 1 is used for determining the location of the region such as a tumor within a patient 3 to be treated and for setting up the sequence of treatment beams. The setup equipment includes a gantry 5 mounted for rotation about a horizontal pivot 7 supported by a machine base 9. A low energy, in the kiloelectronvolt range, x-ray beam 11 is directed by a collimator 13 mounted on the gantry 5 along a path which extends transversely through an extension of the pivot 7.

The patient 3 is supported on a patient positioning assembly 15 which includes a couch 17 mounted on a support 19 for three dimensional translation relative to the support. The support 19, in turn, is mounted on a turntable 21. Through translation of the couch 17, rotation of the turntable 21 and rotation of the gantry 5 about the pivot 7, a plurality of treatment beams can be simulated. By sequencing the simulation equipment 1 through the positions required to generate the successive beams, it can be determined whether all of the required beams can be achieved and whether sequencing the movement of the equipment between beams must be adjusted to avoid collisions between the equipment and the patient or between components of the equipment.

The low energy x-ray beam 11 is used to generate simulation images by placement of an x-ray film 23 in line with the x-ray beam 11 on the other side of the patient 3 from the collimator 13. This simulation image is used to position the area of the patient to be treated, such as a tumor, at the isocenter of the setup, which is the intersection of the beam 11 with a projection of the pivot axis 7.

Following completion of the simulation, the patient 3 is transferred to the treatment setup 1'. As shown, the treatment setup at 1' is similar to the simulation setup 1, except that the x-ray beam 11' is in the megaelectronvolt range. A portal image is generated by the treatment setup 1'. This portal image can be captured by an x-ray film as in the simulation setup; however, it is preferred that an electronic portal imager 25 be used. If available, an electronic imager could also be used in place of the x-ray film 23 in the simulation setup 1.

As discussed above, the simulation image and the portal image can be quite different. One of the main reasons for this is the difference in the energy of the beams 11 and 11'. The invention can be used to match the simulation and portal images to determine if the treatment dosage was delivered to the proper treatment area. It can also be used to detect patient movement during treatment to terminate generation of the x-ray beam 11' if a movement exceeds proper limits, or to maneuver the equipment to maintain proper alignment.

The image matching system 27 includes a digitizer 29 which digitizes the simulation image such as produced on the x-ray film 23 and the portal image such as that generated by the electronic portal imager 25. In a more general sense, the matching system 27 matches an x-ray image, such as the portal image, with a reference image such as the simulation image.

The image matching system 27 further includes a processor 31 which includes a module for coarse alignment 33 followed by a module for fine alignment 35. The output of the processor can be matched portal (x-ray) and simulation (reference) images which are displayed on a display device 37. Associated with the display device 37 are interface devices 39 which can include a keyboard 41 and a pointing device 43, such as a mouse or a trackball.

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FIGS. 2a-2c illustrate that the invention can be used to match a portal x-ray image with a simulation reference image. FIG. 2a represents a simulation image 45 generated using the simulation setup 1. The low energy x-rays used for this image produce an image with good contrast and detail, so that the outline 47 of the patient and bony structure 49 are shown as well as the tumor 51. FIG. 2b illustrates the portal image which being taken with the higher energy treatment beam shows the treated area 55 as a uniform dark spot. The irregular edge of the treated area 55 is produced by the leaves used in the collimator 13 to conform the beam 11' generally to the shape of the tumor. The remainder of the portal image 55 shows little detail and does not indicate the location of the bones. As can be seen, the two images 45 and 53 can be translated relative to each other, scaled differently, skewed and rotated (by 90° in the example). The two images can also be different in perspective and in curvature.

The coarse alignment module 33 produces a general alignment of the two images, and then the fine alignment module 35 uses robust motion flow to rapidly and accurately complete matching of the images. The display device 37 can present the matched images in different ways. In one embodiment, the display 37 alternates between the two images at about 6 to 20 Hz, but usually about 12 Hz, so that the observer views the images superimposed as a composite image 59, as shown in FIG. 2c. As can be seen in the example, the treated area 55' in the matched portal image, overlays the tumor 51' in the matched simulation image. In another type of display (not shown), the outline of the treated area from the portal image is projected onto the processed simulation image, so that it can be seen if the targeted tumor was in fact treated.

In performing the coarse alignment, a coarse transformation is applied to the digitized x-ray or portal image signals (DPIS) to convert them to the coordinate system of the digital reference or simulation image signals (DSIS). As will be seen, the information needed to generate this transformation can be generated interactively through selection of what appear to be corresponding points in the two images by the operator interactively using a pointer device 43 or automatically using x-ray opaque fiducials 61 which are placed on the patient in both the simulation setup and the treatment setup (see FIG. 1). The points so generated in either case are referred to as seed points. The coarse transform H from the portal image coordinates to the simulation coordinates is:

$$\begin{bmatrix} \text{simulation}_x \\ \text{simulation}_y \\ 1 \end{bmatrix} = \begin{bmatrix} \text{RotSkewScale}_x & \text{RotSkewScale}_y & \text{translation}_x \\ \text{RotSkewScale}_y & \text{RotSkewScale}_x & \text{translation}_y \\ 0 & 0 & 1 \end{bmatrix} \cdot \begin{bmatrix} \text{portal}_x \\ \text{portal}_y \\ 1 \end{bmatrix} \quad (\text{EQ. 1})$$

The (x y) vector denotes the column and row coordinates of the center of each of the seed points in the corresponding portal and simulation images. The four RotSkewScale components of the matrix describe the full affine transformation that is needed to coarsely align the images. In this stage, the placement of the fiducial or the interactive selection of the seed points need not be accurate as the next stage is able to accommodate for reasonably small deviations.

Using the results of the coarse alignment, the portal image is warped toward the simulation image. Then, overlapping regions of the two images are computer enhanced so that the

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corresponding intensity levels are similar. Finally, the motion-flow, or the fine-scale transform is computed so that the portal image glides on the gradient of dissimilarity toward the simulation image. In this stage, a more comprehensive transformation model is used in which the input position vector is represented by:

$$\underline{X}(x) = \begin{bmatrix} 1 & x & y & 0 & 0 & 0 & x^2 & x \cdot y & 0 \\ 0 & 0 & 0 & 1 & x & y & x \cdot y & y^2 & x^2 \end{bmatrix} \quad (\text{EQ. 2})$$

and the transformation matrix is represented by:

$$Q = [\alpha_0 \alpha_1 \alpha_2 \alpha_3 \alpha_4 \alpha_5 P_0 P_1 c]^T \quad (\text{EQ. 3})$$

so that the result is:

$$u(x; Q) = X(x) \cdot Q \quad (\text{EQ. 4})$$

where  $\Delta$  portal (x; Q) = u(x; Q) and portal (x) = X(x). The parameters  $\alpha_0$  through  $\alpha_5$  include the affine transform as in the coarse alignment, whereas the parameters  $P_0$ ,  $P_1$  include the perspective transformation, and c covers the deformation that can be caused by breathing, etc.

To recover the parameters of the vector Q we formulate the image dissimilarity as a result of motion-flow, or distance between the two images.

$$I(x, t) = I(x - (X(x) \cdot Q)_{t-1}, t) \quad (\text{EQ. 5})$$

for  $\forall x \in f$ , where f is the region of the image we compute the transformation over. In (EQ. 5), I(x) is the intensity function at point x, the image at t+1 is the portal image, and at t is the simulation image. By using various derivation techniques, we formulate the motion-flow using the gradient (or dissimilarity gradient) as below:

$$\nabla K(X(x) \cdot Q) + \frac{\partial I}{\partial t} = 0 \quad (\text{EQ. 6})$$

for  $\forall x \in f$ .

In this stage, a robust regression method is employed, using unconstrained optimization, to calculate the elements of Q (see (EQ. 3)). This technique enables us to cope with the 'reasonably small' deviations from the coarse alignment stage, as well as any residual dissimilarity between the two images. Using the robust technique ensures that only the dominant transformation will be recovered without running into the risk of being affected by the noise and residual errors.

FIGS. 3-11 are flow charts of software which implements the invention. FIG. 3 illustrates the main routine 100 which includes performing a coarse alignment, either interactively at block 110 or automatically at block 120. In both cases a rough approximation of the transformation between the portal image and the simulation image is calculated using Equation 1. The user then has the option of determining whether the rough approximation has provided a satisfactory alignment of the images at 130. If so, the procedure is completed. If not, a fine alignment is performed. As discussed, the invention can also be used to track patient movement, in which case the transformation between the two images is utilized at 140 to roughly determine the updated position of the fiducials. If requested by the user in image matching and during tracking, the images are prepared for the fine alignment at 150. The refined image transformation is then calculated at 160 and if the image



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matching mode is selected as determined at 170, the transform is accomplished and the images are displayed at 180 in the manner discussed above. If the tracking mode has been selected at 190, the routine returns to 140 for generating the next position. The user again has the final decision at 200 to determine whether the image matching is satisfactory. If not, the routine returns to 110 and the rough calculation is re-initiated.

The procedure for calculating the rough approximation of the transformation interactively called for at block 110 in FIG. 3 is illustrated in detail in FIG. 4. The user selects corresponding seed points or areas in the portal image and the simulation image using, for instance, the mouse 43 as indicated at 111. The selected areas or points are then used to compute the rough transformation between the portal image and the simulation image by calling a procedure A as indicated at 112. This rough transform is then used to transform the portal image to simulation image coordinates by calling procedure B as indicated at 113. The images are then displayed on the monitor 37 as indicated at 114.

The details of procedure A used to calculate the rough transform are shown in FIG. 5. If the user has indicated an area as determined at A1, the system automatically selects random points from inside the area as corresponding as indicated at A2. Then, or if the user has selected points rather than an area, the corresponding point pairs are used to calculate the transform parameters using the least squares (LSQ) method as indicated at A3.

The details of procedure B for transforming the portal to simulation coordinates is shown in FIG. 5. First, the row and column limits of the resulting transformed portal image are determined at B1 using the transformation matrix H, which is the inverse of Equation 1. The resulting portal image is then raster scanned at B2, and for each pixel the location is determined using the transformation. The intensity value for each pixel is calculated next using linear interpolation between the surrounding pixel locations in the original portal image.

The routine 124 for performing the coarse alignment automatically using fiducials on the patient is shown in FIG. 7. The x-ray opaque fiducials 61 are detected in both the portal and simulation images at 121 and the corresponding markers are identified at 122. The image transform is then computed at 123 using procedure A of FIG. 5 and the centroid of each of the markers as the seed points. The portal image is then transformed to simulation coordinates using the computed transformation and procedure B of FIG. 6. When in the matching mode as determined at 125, the images are displayed at 126 in the manner discussed above in connection with FIGS. 2a-c.

The routine 150 for preparing the coarse aligned digital image signals for fine alignment is shown in FIG. 8. First, the region of intersection over overlap between the simulation and portal images is calculated at 151 using the transformation of Equation 1. Next, the largest rectangular region that fits within the intersection region is calculated at 152. Other regular geometric shapes, such as a square and so forth, could be used in place of the rectangle. New images representing the rectangular intersection region of the portal and simulation image are formed at 153. These resulting images are then enhanced at 154 to generate prepared digital image signals. Various forms of enhancement such as histogram equalization, laplacian of the Gaussian, high-pass filtering and other techniques are used to produce the prepared images with similar dynamic range and pixel intensities.

FIG. 9 illustrates the routine 160 for calculating the updated transformation for a fine alignment. This process is

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performed at several levels of resolution of the digital image signals beginning with the lowest resolution, which in the example is about one-eighth resolution. Thus, at 161 the images at the lowest resolution for the prepared portal and simulation images are formed. These images are updated using the latest updated transformation parameters, that is, transformation parameters calculated at the previous level of resolution, at 162. An important part of the invention is that robust motion flow is used to perform the fine alignment. In particular, the motion flow gradient components are generated at 163. Application of motion flow using gradient components is described by M. J. Black and P. Anandan in a paper entitled, "A Framework For The Robust Estimation Of Optical Flow" published in Proc. 4th Intl. Conf. on Computer Vision (ICCV 93), Berlin, Germany, May 1993. Motion flow is applied to the motion required to cause pixels on one image to flow into alignment with corresponding pixels in the other image. Robust motion applies to the motion by which most of the pixels which have moved have moved similarly, while there may be others exhibiting different motion. The updated image transformation parameters are then calculated at 164 using robust optimization. If the upper limit of resolution has not been reached as determined at 165, then the resolution is incremented at 166 and updated transformation parameters are recalculated at the new level of resolution.

When the highest level of resolution has been reached at 165, the final transformation matrix Q is generated at 167. The details of the routine for calculating the updated image transformation parameters using robust optimization of block 164 in FIG. 9 is shown in FIG. 10. As described in the paper by Black and Anandan discussed above, the robust motion is represented by data points called inliers. Those exhibiting other motion are identified as outliers. In the present invention, the data points are the pixel values. The pixels are successively separated into inliers and outliers based upon their contribution to a consistent motion flow vector. The pixels in the inlier set are used to calculate the dominant motion flow, and their contribution to it is dependent on their weight factors which are calculated during the robust optimization.

Referring particularly to FIG. 10, a loop is entered at 164.1 where each of the inlier points is marked using individual weight factors. Initially, the weight factors of the pixels are all set to 1 so that all of the pixels are inliers. At 164.2, an optimization parameter,  $\sigma$ , which determines the sensitivity of the procedure to outliers is set. The weight factors are dependent on this parameter,  $\sigma$ . The lower the value of  $\sigma$ , the more points are eliminated as inliers and the closer the inliers become to the current estimate of the motion flow vector. Hence, a large  $\sigma$  is used initially so that all points are included. On successive loops,  $\sigma$  is lowered to eliminate more and more outliers. This lowering of  $\sigma$  is referred to as  $\sigma$  scheduling. The  $\sigma$  scheduling must be done carefully. If  $\sigma$  is lowered too fast, a solution may be missed, while on the other hand, lowering  $\sigma$  too slowly increases the processing time. In accordance with the invention,  $\sigma$  is lowered depending upon the largest error in the motion flow parameters. Following this, another loop is entered at 164.3 in which each of the inlier data points is used in the calculation of the updated values for the transformation parameters of the Q matrix at 164.4. The equations used at 164.4 are derived preferably using the conjugate gradient, although gradient descent can also be used. In addition, motion flow and robust statistics are used in deriving equations for determining the transformation parameters. The error in the transformation parameters, which is the change

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from the last calculation, as well as  $\sigma$ , are used at 164.5 to adjust the weight factors for the pixels. When all of the inlier data points/pixels have been used as determined at 164.3, a check is made at 164.6 to determine if the solution has converged to the desired degree. If not, the routine returns to 164.1 and the inlier data points are again marked using the updated weight factors.

FIG. 11 illustrates the tracking routine on 140. As indicated at 141, the incremental updates and the transform H and/or Q are combined so that the transform always relates back to the original simulation or reference image. On the initial pass through the tracking routine, the then current portal image replaces the simulation image if used, and then a new portal image is acquired at 143. As tracking continues, successive portal images are matched with the next preceding portal image to generate the updated transform. As indicated at 144, the successive positions of the fiducials or changes in the pattern of the fiducials from successive portal images is used to generate tracking signals for controlling the radiotherapy equipment such as turning the beam on and off and/or driving the patient positioning assembly.

While specific embodiments of the invention have been described in detail, it will be appreciated by those skilled in the art that various modifications and alternatives to those details could be developed in light of the overall teachings of the disclosure. Accordingly, the particular arrangements disclosed are meant to be illustrative only and not limiting as to the scope of invention which is to be given the full breadth of the claims appended and any and all equivalents thereof.

What is claimed is:

1. Apparatus for automatically matching a portal image with a simulation image, said apparatus comprising:

means digitizing said portal image and simulation image to generate digital portal image signals (DPIS) and digital simulation image signals (DSIS), respectively; processing means processing said DPIS and said DSIS to generate matched DPIS and DSIS; and

output means for generating an output from said matched DPIS and DSIS.

2. The apparatus of claim 1, wherein said processing means comprises coarse alignment means generating coarse aligned DPIS and DSIS from said DPIS and DSIS, and fine alignment means generating said matched DPIS and DSIS from said coarse aligned DPIS and DSIS for overlapping regions of said simulation and portal images.

3. The apparatus of claim 2, wherein said coarse alignment means comprises means selecting corresponding seed points in said portal image represented by said DPIS and said simulation image represented by said DSIS, means computing a transform between said portal image and said simulation image from said corresponding seed points, and means applying said transform to one of said DPIS said DSIS to generate with the other of said DPIS and DSIS said coarse aligned DPIS and DSIS.

4. The apparatus of claim 3, wherein said means selecting corresponding seed points comprises interactive means selecting corresponding points in displays generated from said DPIS and DSIS.

5. The apparatus of claim 3, wherein said means selecting corresponding seed points comprises means detecting x-ray opaque fiducials in said DPIS and said DSIS, and means identifying corresponding fiducials in said DPIS and DSIS as said corresponding seed points.

6. The apparatus of claim 3, wherein said fine alignment means comprises means generating prepared DPIS and DSIS from said coarse aligned DPIS and DSIS, means

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generating an updated transform from said prepared DPIS and DSIS, and means applying said updated transform to one of said coarse and prepared DPIS and DSIS to generate said matched DPIS and DSIS.

7. The apparatus of claim 2, wherein said fine alignment means comprises means generating prepared DPIS and DSIS from said coarse aligned DPIS and DSIS, means generating an updated transform from said prepared DPIS and DSIS, and means applying said updated transform to one of said coarse and prepared DPIS and DSIS to generate said matched DPIS and DSIS.

8. The apparatus of claim 7, wherein said means generating said prepared DPIS and DSIS comprises means selecting selected DPIS and selected DSIS for regions of images represented by said DPIS and DSIS which intersect.

9. The apparatus of claim 8, wherein said means generating said prepared DPIS and DSIS further includes means enhancing said selected DPIS and DSIS.

10. The apparatus of claim 9, wherein said means selecting said selected DPIS and selected DSIS further includes means selecting DPIS and DSIS within a portion of regions of images represented by said DPIS and DSIS, which have a predetermined regular shape.

11. The apparatus of claim 7, wherein said means generating said updated transform comprises means generating motion flow components from said prepared DPIS and DSIS and calculating means calculating said updated transform from said motion flow components.

12. The apparatus of claim 11, wherein said means generating motion flow components generates motion flow gradient components, and said calculating means comprises means applying a robust optimization to calculate said updated transform.

13. The apparatus of claim 12, wherein said means generating said updated transform comprises utilizing said means generating motion flow gradient components and said calculating means repetitively using successive ascending levels of resolution of said prepared DPIS and DSIS.

14. The apparatus of claim 7, wherein said means generating said updated transform comprises means using successive ascending levels of resolution of said prepared DPIS and DSIS to generate said updated transform.

15. The apparatus of claim 7, wherein said means generating said updated transform comprises means applying robust motion flow to said prepared DPIS and DSIS.

16. The apparatus of claim 15, wherein said means applying robust motion flow to said prepared DPIS and DSIS applies robust motion flow to successive ascending levels of resolution of said DPIS and DSIS.

17. The apparatus of claim 1, wherein said output means comprises display means generating a display from said matched DPIS and DSIS.

18. The apparatus of claim 1, wherein said output means comprises tracking means tracking movement in said image represented by said DPIS.

19. The apparatus of claim 18, wherein said output means further includes positioning means positioning a patient relative to a radiation beam which generates said portal image, and means controlling said positioning means in response to movement tracked by said tracking means.

20. The apparatus of claim 18 wherein said output means includes means controlling generation of a radiation beam producing said portal image in response to movement tracked by said tracking means.

21. Apparatus for matching portal images to control radiotherapy/diagnosis equipment, said apparatus comprising:

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means digitizing successive portal images to generate successive sets of digital portal image signals (DPIS); and

tracking means tracking movement between successive sets of DPIS.

22. The apparatus of claim 21, wherein said tracking means comprises means generating an updated transform between successive portal images by applying robust motion flow to said successive sets of DPIS and means using said updated transform to track said movement between said successive sets of DPIS.

23. The apparatus of claim 22, wherein said means generating said updated transform comprises means generating motion flow components from said successive sets of DPIS, and means calculating said updated transform between successive portal images using said motion flow components.

24. The apparatus of claim 23, wherein said means generating motion flow components generates motion flow gradient components, and wherein said calculating means comprises means applying a robust optimization to calculate said updated transform.

25. The apparatus of claim 24, wherein said means generating said updated transform comprises means utilizing said means generating motion flow gradient components and said calculating means repetitively using successive ascending levels of resolution of said successive sets of DPIS.

26. Apparatus for automatically matching an x-ray image with a reference image, said apparatus comprising:

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means digitizing said x-ray image and reference image to generate first digital image signals and second digital image signals, respectively;

5 processing means processing said first and second digital signals without input of any physical dimensions of any features within said images to generate matched digital image signals; and

10 display means generating a display from said matched digital image signals.

27. The apparatus of claim 26 wherein said processing means comprises coarse alignment means generating coarse aligned digital images signals from said first and second digital image signals, and fine alignment means generating a transform between said coarse aligned digital image signals for overlapping regions of said x-ray and reference images utilizing robust motion flow, and means applying said transform to one of said coarse aligned digital image signals to generate said matched digital image signals.

28. The apparatus of claim 27 wherein said fine alignment means comprises means enhancing said coarse aligned digital image signals to generate prepared coarse aligned image signals having similar dynamic ranges and intensities, and means generating said transform between said prepared coarse aligned digital image signals utilizing robust motion flow.

\* \* \* \* \*

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

Page 1 of 2

**PATENT NO.** : 5,784,431  
**DATED** : July 21, 1998  
**INVENTOR(S)** : Kalend, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

At [56] References Cited, please add the following patents and publications.

OTHER DOCUMENTS

		<i>Digital portal image registration by sequential anatomical matchpoint and image</i>
		<i>correlations for real-time continuous field alignment verification</i> , Brian J. McPartland and J. Carl Kumaradas, Phys. 22(7), July 1995, pp. 1063-1075.
		<i>Neural Network Object Recognition for Inspection of Patient Setup in Radiation Therapy</i>
		<i>Using Portal Images</i> , Susan S. Young, et al., 1996 IEEE, pp. 3418-3421.

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

Page 2 of 2

PATENT NO. : 5,784,431  
DATED : July 21, 1998  
INVENTOR(S) : Kalend, et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Column 9, line 37, after "means" insert --comprising coarse alignment means--.

Column 9, line 38, after "generate" insert --coarse aligned DPIS and DSIS, means determining from said coarse aligned DPIS and DSIS overlapping regions of said simulation and portal images, and fine alignment means generating--.

Column 9, line 38, after "DSIS" insert --from said coarse aligned DPIS and DSIS for said overlapping regions of said simulation and portal images--.

Cancel Claim 2.

Column 9, line 47, change "2" to --1--.

Column 10, line 5, change "2" to --1--.

Signed and Scaled this

Twenty-third Day of February, 1999

Attest:



Q. TODD DICKINSON

Attesting Officer

Acting Commissioner of Patents and Trademarks



# **EXHIBIT B**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

UNIVERSITY OF PITTSBURGH,

Plaintiff,

v.

VARIAN MEDICAL SYSTEMS, INC.,

Defendant.

Civil Action No. 2:07-cv-00491-AJS

Judge Arthur J. Schwab

**FILED ELECTRONICALLY**

**PROTECTIVE ORDER**

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, the following Protective Order has been entered by Court.

**Proceedings and Information Governed.**

1. This Order and any amendments or modifications hereto ("Protective Order") shall govern any document, material, testimony, information or other thing furnished by any party, to any other party, and includes non-parties who receive a subpoena in connection with this action. The information protected includes, but is not limited to, answers to interrogatories, answers to requests for admission, responses to requests for production of documents, responses to subpoenas, deposition transcripts and videotapes, deposition exhibits, and other writings or things produced, given or filed in this action that are designated by a party as "Confidential", "Confidential Attorney Eyes Only" or "Confidential Attorney Eyes Only – Source Code" in accordance with the terms of this Order, as well as to any copies, excerpts, abstracts, analyses, summaries, descriptions, or other forms of recorded information containing, reflecting, or disclosing such information.

**Designation and Maintenance of Information.**

2. For purposes of this Protective Order, (a) the "Confidential Information" designation shall mean that the document is comprised of trade secrets or commercial information which is not publicly known and is of technical or commercial advantage to its possessor, in accordance with Fed.R.Civ.P. 26(c)(7), or other information required by law or agreement to be kept confidential, (b) the "Confidential Attorney Eyes Only" designation shall mean that the document is comprised of information that the producing party deems especially sensitive, which may include, but is not limited to, confidential research and development, financial, technical, marketing, any other sensitive trade secret information, or information capable of being utilized for the preparation, or prosecution of a patent application dealing with such subject matter and (c) the "Confidential Attorney Eyes Only – Source Code" designation shall mean that the material contains "Source Code" which, for the purposes of this Order, means both human (commented) and machine readable program codes and software that the designating party believes in good faith is not generally known to others and has significant competitive value such that unrestricted disclosure to others would create a substantial risk of serious injury, and which the designating party (i) would not normally reveal to third parties except in confidence or has undertaken with others to maintain in confidence, or (ii) believes in good faith is significantly sensitive and protected by a right to privacy under federal or state law or any other applicable privilege or right related to confidentiality or privacy. Confidential, Confidential Attorney Eyes Only and Confidential Attorney Eyes Only - Source Code information does not include, and this Protective Order shall not apply to, information that is already in the knowledge or possession of the party to whom disclosure is made unless that party is already bound by agreement not to disclose such information, or information that has been disclosed to the public or third persons in a manner making such information no longer confidential.

3. Documents and things produced during the course of this litigation within the scope of paragraph 2 (a) above, may be designated by the producing party as containing Confidential Information by placing on each page and each thing a legend substantially as follows:

**CONFIDENTIAL INFORMATION  
SUBJECT TO PROTECTIVE ORDER**

(a) Documents and things produced during the course of this litigation within the scope of paragraph 2(b) above may be designated by the producing party as containing Confidential Attorney Eyes Only Information by placing on each page and each thing a legend substantially as follows:

**CONFIDENTIAL ATTORNEY EYES ONLY INFORMATION  
SUBJECT TO PROTECTIVE ORDER**

(b) Documents and things produced during the course of this litigation within the scope of paragraph 2(c) above may be designated by the producing party as containing Attorney Eyes Only - Source Code Information by placing on each page and each thing a legend substantially as follows:

**CONFIDENTIAL ATTORNEY EYES ONLY - SOURCE CODE INFORMATION  
SUBJECT TO PROTECTIVE ORDER**

A party may designate information disclosed at a deposition as Confidential Information, Confidential Attorney Eyes Only Information or Confidential Attorney Eyes Only - Source Code by requesting the reporter to so designate the transcript or any portion thereof at the time of the deposition. If no such designation is made at the time of the deposition, any party shall have fourteen (14) calendar days after the date of the deposition to designate, in writing to the other parties and to the court reporter, whether any part of the transcript is to be designated as Confidential Information, Confidential Attorney Eyes Only Information or Attorney Eyes Only -

Source Code. All counsel receiving such notice shall be responsible for marking the copies of the designated transcript or portion thereof in their possession or under their control as Confidential, Confidential Attorney Eyes Only Information, or Confidential Attorney Eyes Only - Source Code. If no such designation is made at the deposition or within such fourteen (14) calendar day period (during which period, the transcript shall be treated as Confidential Attorney Eyes Only, unless the disclosing party consents to less confidential treatment of the information), the entire deposition will be considered devoid of Confidential Information, Confidential Attorney Eyes Only Information or Confidential Attorney Eyes Only - Source Code. Each party and the court reporter shall attach a copy of any final and timely written designation notice to the transcript and each copy thereof in its possession, custody or control, and the portions designated in such notice shall thereafter be treated in accordance with this Protective Order.

It is the responsibility of counsel for each party to maintain materials containing Confidential Information, Confidential Attorney Eyes Only Information or Confidential Attorney Eyes Only - Source Code in a secure manner and appropriately identified so as to allow access to such information only to such persons and under such terms as is permitted under this Protective Order.

4. The protections conferred by this Order cover not only designated material as described herein, but also any information copied or extracted therefrom, as well as all copies, excerpts, summaries, or compilations thereof.

**Inadvertent Failure to Designate.**

5. The inadvertent failure to designate or withhold any information as confidential or privileged will not be deemed to waive a later claim as to its confidential or privileged nature, or to stop the producing party from designating such information as confidential at a later date in

writing and with particularity. The information shall be treated by the receiving party as confidential from the time the receiving party is notified in writing of the change in the designation.

**Inadvertent Production of Privileged Information.**

6. The inadvertent production of privileged information will not be deemed to waive the attorney-client privilege or protection under the attorney work product doctrine. Upon discovering an inadvertent production of such information, the producing party shall promptly notify the receiving party. The receiving party must return within five calendar days, the original produced copy to the producing party, destroy all copies, provide verification of destruction and provide the producing party with a list of those individuals who reviewed the privileged information within five (5) calendar days of receiving notice from the producing party. This right to retrieve inadvertently produced privileged information extinguishes thirty (30) calendar days prior to the pre-trial conference.

**Challenge to Designations.**

7. A receiving party may challenge a producing party's designation at any time. Any receiving party disagreeing with a designation may request in writing that the producing party change the designation. The producing party shall then have ten (10) business days after receipt of a challenge notice to advise the receiving party whether or not it will change the designation. If the parties are unable to reach agreement after the expiration of this ten (10) business day timeframe, and after the conference required under Local Rule 37.1, the receiving party may at any time thereafter seek a Court Order to alter the confidential status of the designated information. Until any dispute under this paragraph is ruled upon by the Court, the designation

shall remain in full force and effect and the information shall continue to be accorded the confidential treatment required by this Protective Order.

**Disclosure and Use of Confidential Information.**

8. Information designated as Confidential Information, Confidential Attorney Eyes Only Information or Confidential Attorney EyesOnly - Source Code Information may only be used for purposes of preparation, trial and appeal of this action. Confidential Information, Confidential Attorney Eyes Only Information or Confidential Attorney EyesOnly - Source Code Information may not be used under any circumstances for prosecuting any patent application, for patent licensing or for any other purpose.

9. Subject to paragraph 13 below, Confidential Information may be disclosed by the receiving party only to the following individuals provided that such individuals are informed of the terms of this Protective Order: (a) two (2) employees of the receiving party who are required in good faith to provide assistance in the conduct of this litigation, including any settlement discussions, and who are identified as such in writing to counsel for the designating party in advance of the disclosure; (b) two (2) in-house counsel who are identified by the receiving party; (c) outside counsel for the receiving party; (d) supporting personnel employed by (b) and (c), such as paralegals, legal secretaries, data entry clerks, legal clerks and private photocopying services; (e) experts or consultants; and (f) any persons requested by counsel to furnish services such as document coding, image scanning, mock trial, jury profiling, translation services, court reporting services, demonstrative exhibit preparation, or the creation of any computer database from documents.

10. Subject to paragraph 13 below, Confidential Attorney Eyes Only Information may be disclosed by the receiving party only to the following individuals provided that such individuals

are informed of the terms of this Protective Order: (a) outside counsel for the receiving party; (b) supporting personnel employed by (a), such as paralegals, legal secretaries, data entry clerks, legal clerks, private photocopying services; (c) experts or consultants; and (d) those individuals designated in paragraph 15(c).

11. Subject to paragraph 13 below, Confidential Attorney Eyes Only – Source Code Information may be disclosed by the receiving party only to the following individuals provided that such individuals are informed of the terms of this Protective Order: (a) outside counsel for the receiving party; (b) supporting personnel employed by (a), such as paralegals, legal secretaries, data entry clerks, legal clerks, private photocopying services; (c) experts or consultants; and (d) those individuals designated in paragraph 15(c). Unless otherwise agreed to in writing between the producing party and the receiving party, Attorney Eyes Only - Source Code Information shall only be provided on stand-alone computers (that is, computers not connected to a network, Internet or a peripheral device) at secure locations, to be made available during regular business hours on reasonable notice.

12. The producing party will allow printing of paper copies of specific portions of Source Code designated as “Confidential Attorney Eyes Only - Source Code Information” at the time of inspection by the receiving party, which the receiving party may take when completing an inspection. During an inspection, the receiving party may also identify sections or modules of code, which will be printed by the producing party and shipped to the receiving party’s Outside Counsel of Record. The party receiving paper copies of any Source Code designated as “Confidential Attorney Eyes Only - Source Code Information”, whether printed at the time of inspection or produced in such paper form, must keep that Source Code in a secured container when not in use at the receiving party’s Outside Counsel of Record. The receiving party shall



maintain a complete log of Bates numbered pages printed and persons who have reviewed those pages, and shall produce such log at the time its first expert reports relating to source code are delivered, regardless of the restrictions on expert discovery below. For security purposes, this log must be produced to the producing party regardless of any other stipulation limiting expert discovery. Further, the log will be supplemented with each new expert report relating to Source Code, 10 days after trial, and at the termination of this action.

13. Further, prior to disclosing Confidential Information, Confidential Attorney Eyes Only Information or Confidential Attorney Eyes Only - Source Code Information to a receiving party's proposed expert, consultant or employees, the receiving party shall provide to the producing party a signed Confidentiality Agreement in the form attached as Exhibit A, the resume or curriculum vitae of the proposed expert or consultant, the expert or consultant's business affiliation, and any current and past consulting or employment relationships in the industry. The producing party shall thereafter have ten (10) business days from receipt of the Confidentiality Agreement to object to any proposed individual. Such objection must be made for good cause and in writing, stating with particularity the reasons for objection. Failure to object within ten (10) business days shall constitute approval. If the parties are unable to resolve any objection, the receiving party may apply to the Court to resolve the matter. There shall be no disclosure to any proposed individual during the ten (10) business day objection period, unless that period is waived by the producing party, or if any objection is made, until the parties have resolved the objection, or the Court has ruled upon any resultant motion.

14. Counsel shall be responsible for the adherence by third-party vendors to the terms and conditions of this Protective Order. Counsel may fulfill this obligation by obtaining a signed Confidentiality Agreement in the form attached as Exhibit B.

15. Confidential Information, Confidential Attorney Eyes Only Information or Confidential Attorney Eyes Only - Source Code Information may be disclosed to a person, not already allowed access to such information under this Protective Order, if:

- (a) the information was previously received or authored by the person or was authored or received by a director, officer, employee or agent of the company for which the person is testifying as a Rule 30(b)(6) designee;
- (b) the designating party is the person or is a party for whom the person is a director, officer, employee, consultant or agent; or
- (c) counsel for the party designating the material agrees that the material may be disclosed to the person. In the event of disclosure under this paragraph, only the reporter, the person, his or her counsel, the judge and persons to whom disclosure may be made, and who are bound by the Protective Order, may be present during the disclosure or discussion of Confidential/Confidential Attorney Eyes Only/ Confidential Attorney Eyes Only - Source Code Information. Disclosure of material pursuant to this paragraph shall not constitute a waiver of the confidential status of the material so disclosed.

**Non-Party Information.**

16. The existence of this Protective Order shall be disclosed to any person producing documents, tangible things or testimony in this action who may reasonably be expected to desire confidential treatment for such documents, tangible things or testimony. Any such person may designate documents, tangible things or testimony confidential pursuant to this Protective Order.

**Filing Documents With the Court.**

17. In the event that any party wishes to submit "Confidential," "Confidential Attorney Eyes Only" or "Confidential Attorney Eyes Only - Source Code" Information to the Court, such a submission shall be filed only in a sealed envelope bearing the caption of this action and a notice in the following form:

**CONFIDENTIAL INFORMATION**

[caption]

This envelope, which is being filed under seal,  
contains documents that are subject to a Protective  
Order governing the use of confidential discovery material.

**No Prejudice.**

18. Producing or receiving confidential information, or otherwise complying with the terms of this Protective Order, shall not (a) operate as an admission by any party that any particular Confidential Information contains or reflects trade secrets or any other type of confidential or proprietary information; (b) prejudice the rights of a party to object to the production of information or material that the party does not consider to be within the scope of discovery; (c) prejudice the rights of a party to seek a determination by the Court that particular materials be produced; (d) prejudice the rights of a party to apply to the Court for further protective orders; or (e) prevent the parties from agreeing in writing to alter or waive the provisions or protections provided for herein with respect to any particular information or material.

Use.

19. The attorneys of record shall employ reasonable measures to control, consistent with this Order, duplication of, access to, and distribution of information designated in accordance with this Order as "Confidential," "Confidential Attorney Eyes Only" or "Confidential Attorney Eyes Only - Source Code" Information. Parties to this action (other than the party which designated the material) shall not duplicate any designated material except for working copies and copies for filing in Court under seal. Designated material shall be used by the party and persons to whom it is disclosed solely in conducting this action and any appellate

proceeding related thereto. Designated material shall not be used by such party or persons for any business or other purpose, unless agreed to in writing by all parties to this action or as authorized by further Order of the Court. No person who is furnished Designated material shall disclose it to any person not entitled under this Order to receive it.

**Party's Own Information.**

20. The restriction on the use of "Confidential," "Confidential Attorney Eyes Only" or "Confidential Attorney Eyes Only - Source Code" information established by this Protective Order are applicable only to the use by the receiving party. The designating party is free to do whatever it desires with its own documents and things.

Depositions.

21. Any deposition reporter who records testimony in this action at a deposition shall be given a copy of this Order and shall be required to agree on the transcript of the deposition, before recording any such testimony, that all testimony and information revealed at the deposition shall not be disclosed by such reporter or any person who transcribed such testimony except to the deponent, the attorneys of record for the parties in this action and their staff.

**Exclusion from Deposition.**

22. Whenever any Confidential/Confidential Attorney Eyes Only/ Confidential Attorney Eyes Only - Source Code material is to be discussed or disclosed in a deposition, any party claiming such confidentiality may exclude from the room any person who is not entitled to receive documents, information or other things designated as Confidential/Confidential Attorney Eyes Only/Confidential Attorney Eyes Only - Source Code.

**Subpoena by other Courts or Agencies.**

23. If another court or an administrative agency subpoenas or orders production of documents or other information designated as Confidential/Confidential Attorney Eyes Only/ Confidential Attorney Eyes Only - Source Code which a party has obtained under the terms of this Order, such party shall promptly notify the party or other person who designated the Confidential material of the pendency of such subpoena or order.

**Logistics of Production.**

24. The parties shall produce digital information in electronic format (e.g., on CDs or DVDs). The producing party will bear the cost of preserving, producing, and restoring any digital information produced and the requesting party will bear the cost of printing any such digital information received.

**Conclusion of Litigation.**

25. Within sixty (60) calendar days of final disposition of this action, whether by judgment, settlement or otherwise, each party or other person subject to the terms of this Protective Order shall be under an obligation to destroy or return to the producing party all materials and documents containing Confidential Information, Confidential Attorney Eyes Only Information or Confidential Attorney Eyes Only - Source Code and to certify to the producing party such destruction or return. However, outside counsel for any party shall be entitled to retain all court papers, trial transcripts, exhibits and attorney work product provided that any such materials are maintained and protected in accordance with the terms of this Protective Order. For the purpose of this paragraph only, "final disposition" includes the last date a notice of appeal may be filed, or issuance of any final appellate decision.

**Other Proceedings.**

26. By entering this Order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or parties subject to this Protective Order that may be subject to a motion to disclose another party's information designated Confidential pursuant to this Protective Order, shall promptly notify that party of the motion so that it may have an opportunity to appear and be heard on whether that information should be disclosed.

**Remedies.**

27. It is Ordered by the Court that this Protective Order will be enforced by the sanctions set forth in Rule 37(b) of the Federal Rules of Civil Procedure and such other sanctions as may be available to the Court, including the power to hold parties or other violators of this Protective Order in contempt. All other remedies available to any person(s) injured by a violation of this Protective Order are fully reserved.

28. Any party may petition the Court for good cause shown, in the event such party desires relief from a term or condition of this Order.

**Exhibit A**

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNIVERSITY OF PITTSBURGH,

Plaintiff,

v.

VARIAN MEDICAL SYSTEMS, INC.,

Defendant.

ELECTRONICALLY FILED

Civil Action No. 2:07-cv-00491-AJS

Judge Arthur J. Schwab

**CONFIDENTIALITY AGREEMENT FOR EXPERT,  
CONSULTANT OR EMPLOYEES OF ANY PARTY**

I hereby affirm that:

Information, including documents and things, designated as "Confidential Information,," "Confidential Attorney Eyes Only Information," or "Confidential Attorney Eyes Only - Source Code" as defined in the Protective Order entered in the above-captioned action (hereinafter "Protective Order"), is being provided to me pursuant to the terms and restrictions of the Protective Order.

I have been given a copy of and have read the Protective Order.

I am familiar with the terms of the Protective Order and I agree to comply with and to be bound by such terms.

I submit to the jurisdiction of this Court for enforcement of the Protective Order.

I agree not to use any Confidential Information, Confidential Attorney Eyes Only Information or Confidential Attorney Eyes Only - Source Code Information disclosed to me pursuant to the Protective Order except for purposes of the above-captioned litigation and not to disclose any such information to persons other than those specifically authorized by said

Protective Order, without the express written consent of the party who designated such information as confidential or by order of this Court. I also agree to notify any stenographic, clerical or technical personnel who are required to assist me of the terms of this Protective Order and of its binding effect on them and me.

I understand that I am to retain all documents or materials designated as or containing Confidential Information, Confidential Attorney Eyes Only Information or Confidential Attorney Eyes Only - Source Code Information in a secure manner, and that all such documents and materials are to remain in my personal custody until the completion of my assigned duties in this matter, whereupon all such documents and materials, including all copies thereof, and any writings prepared by me containing any Confidential Information, Confidential Attorney Eyes Only Information or Confidential Attorney Eyes Only - Source Code Information are to be returned to counsel who provided me with such documents and materials.

I declare under penalty of perjury that the foregoing is true and correct and that this Exhibit A was executed this \_\_\_\_\_ day of \_\_\_\_\_, 2007 at

\_\_\_\_\_.

\_\_\_\_\_



Exhibit B

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNIVERSITY OF PITTSBURGH,	:	<b>ELECTRONICALLY FILED</b>
	:	
Plaintiff,	:	Civil Action No. 2:07-cv-00491-AJS
	:	
v.	:	Judge Arthur J. Schwab
	:	
VARIAN MEDICAL SYSTEMS, INC.,	:	
	:	
Defendant.	:	

**CONFIDENTIALITY AGREEMENT FOR THIRD-PARTY VENDORS**

I hereby affirm that:

Information, including documents and things, designated as "Confidential Information," "Confidential Attorney Eyes Only Information," or "Confidential Attorney Eyes Only – Source Code Information" as defined in the Protective Order entered in the above-captioned action (hereinafter "Protective Order"), is being provided to me pursuant to the terms and restrictions of the Protective Order.

I have been given a copy of and have read the Protective Order.

I am familiar with the terms of the Protective Order and I agree to comply with and to be bound by such terms.

I submit to the jurisdiction of this Court for enforcement of the Protective Order.

I agree not to use any Confidential Information, Confidential Attorney Eyes Only Information or Confidential Attorney Eyes Only – Source Code Information disclosed to me pursuant to the Protective Order except for purposes of the above-captioned litigation and not to disclose any such information to persons other than those specifically authorized by said

Protective Order, without the express written consent of the party who designated such information as confidential or by order of this Court.

I declare under penalty of perjury that the foregoing is true and correct and that this Exhibit B was executed this \_\_\_\_\_ day of \_\_\_\_\_, 2007 at

\_\_\_\_\_.

\_\_\_\_\_

**CERTIFICATE OF SERVICE**

I hereby certify that a true and correct copy of the PROTECTIVE ORDER (which has been electronically filed and is available for viewing and downloading from the ECF system) has been served upon all parties either individually or through counsel via:

_____	Hand-Delivery
_____	Facsimile
_____	First Class, US Mail, Postage Prepaid
_____	Certified Mail-Return Receipt Requested
_____X_____	ECF Electronic Service

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Dated: May 24, 2007

/s/ Henry M. Sneath

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**From:** ecf\_intake\_pawd@pawd.uscourts.gov  
**Sent:** Thursday, May 24, 2007 9:19 AM  
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**U.S. District Court**

**Western District of Pennsylvania**

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**Case Number:** 2:07-cv-491  
**Filer:** UNIVERSITY OF PITTSBURGH  
VARIAN MEDICAL SYSTEMS, INC.  
**Document Number:** 29

**Docket Text:**

Proposed Order (*Protective Order*) by UNIVERSITY OF PITTSBURGH, VARIAN MEDICAL SYSTEMS, INC.. (Sneath, Henry)

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4b3c0f5afff43e6b34eb67166617cdc8afd06f1c902b549a6fa680b941bf]]

**2:07-cv-491 Notice will be electronically mailed to:**

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